Medicolegal

Problems and Solutions

A Doctor's and Practitioner's Guide

Editors

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Alka Kuthe

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CBSPD Dedicated to Education

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Preface

History of medical practice is very old, but it has changed forms. Previously, it was an art, then it became a science and now it is a profession. The very first systematic treatise on doctor–patient relationship was written by Hippocrates in 400 BC and is in practice around the world, although *Charak Samhita* is also claimed to be a doctor–patient treatise predating Hippocratic Oath. In modern times, Hippocratic Oath in its original form in not practical so a modern version of this oath has been drafted and is in use globally. Doctor–patient relationship (DPR) has changed drastically since the second half of the last century. Till the previous half of 20th century doctors had the status of demigods, but in the second half this scene began to change. Patient autonomy gradually increased and doctor's role as demigod/parent and patient's role as subject/child gradually gave way to doctor patient partnership with equal rights. Further changes came with the introduction of Consumer Protection Act in 1986*. This change brought the trend of defensive practice among doctors and made doctor patient relationship more formal.

In the last few decades, a general decline in the status of the doctor, mob harassment and lawsuits have increased exponentially, contributing to even more strained doctor–patient relationship. There was a growing need for a quick reference book to look for solutions in case of a myriad of medicolegal situations. This book has been brought out keeping that need in mind.

Most doctors are slow to adopt to the changing scenario. Despite being good in their profession, when it comes to taking due measures to avoid mistakes or to handle a medicolegal situation, few are able to face the situation adeptly. Record keeping, informed consent, and documentation form the basis of safe medical practice. Unexpected death in hospital or OT is a tricky issue and how to deal with it, how to manage the mob and media, when to send for PM, how to do documentation in such cases, are all incorporated in the book.

This book contains 44 chapters based on day-to-day medicolegal issues, by authors with expertise in medicolegal knowledge and patient care have been incorporated in this state-of-the-art book. The book is divided into eight sections, viz. Critical Patients, Procedural Complications, Errors, and Unexpected Outcome, Difficult Situations, Statutory Situations, Negligence, Administrative Problems and Miscellaneous.

We hope this book fulfills the expectations of not only the practicing doctors but also the undergraduate and postgraduate students, medicolegal consultants and other stakeholders. We have tried to cover most of the situations in daily practice, but if some important topics are left out the distinguished readers shall feel free to inform so that the same can be incorporated in future editions. The editorial team welcomes the reviews, comments, suggestions and constructive criticism from the learned and knowledgeable readers about this manuscript.

Editorial Team

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* Consumer Protection Act, 1986 has been repealed and replaced by Consumer Protection Act, 2019

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Chapter
1

Seriously Ill Patients: Medicolegal and Ethical Issues

Shivakumar F Kumbar

INTRODUCTION

The approach to the management of seriously ill patient has been strongly influenced by advances in sciences and technology, ethics, law, recognition of rights of the patients and social changes. At present, decision making is modulated by ethical and legal considerations. We have to consider basic values of autonomy, beneficence, non-maleficence, justice.

During the past few decades seriously ill patients management is strongly influenced by above considerations. At the bed side, ethical and legal considerations make vital role and has become fundamental challenge in the practice of medicine.

Ethical Principles

1. **Principle of double effect:** It is considered when obligations or values conflict and cannot be released simultaneously. According to this there is a moral difference between the intended effects of a person's action and unintentional, but foreseen effects of action. The desirable effect (good) is linked to an undesirable effect (bad). The good effect is direct and intended, whereas the foreseen undesirable effect is indirect and not intended.
2. **Treatment decision:** It is a combination of medical, emotional, aesthetic, religious, philosophical, social, interpersonal and personal judgment.
3. **The cure and care systems** are not mutually exclusive but rather overlap.
4. **Proportionality principle** states that a medical treatment is ethically mandatory to the extent that it is likely to confer greater benefits than burdens upon the patient.

Decision-making Considerations

1. **Futility:** The medical profession has no obligation to provide futile or unnecessary treatment. The futility takes into consideration, the purpose of therapy, its chances of success (quantitative aspect), and balance of burdens and benefits (qualitative aspect). The treatment is probably not futile, if there is a real chance of achieving some desirable end, which is cure of the patient, patient comfort, patient dignity or even comfort to the family. The question about futility may be raised in cardiopulmonary resuscitation (CPR) of terminally ill patients, seriously ill patients, persistent vegetative state patient and use of total parenteral nutrition in seriously ill patients.

2. **Informed consent**.
3. **Decision making for the incompetent:** If the patient lacks capacity someone must be designated to make decisions on the patients behalf. This person may be guardian, health care agent, surrogate.
4. **Advanced directives:** These can be oral or written instructions specifying the wishes of a person concerning medical treatment in anticipation of future in capacity. The most common types of advance directives are—living will and durable power of attorney which can be general or specific.
5. **Withholding and withdrawing therapy:** This is considered when treatment in seriously ill patient is medically futile. Withholding occurs when the treatment is not provided. Withdrawing is defined as ending treatment that has no demonstrated value.
6. **Do not-attempt resuscitation (DNAR) order:** Physicians have the obligation to clarify patient wishes concerning CPR, but there are numerous problems in communication and implementation of DNR. A patient who is for DNR can still continue treatment.

In certain situations, providing CPR is likely to increase suffering of patients who have serious illness and without the prospect of reasonable quality of life even if they are reviewed. DNAR is an option that may be exercised by the treating physician in the best interest of the patient. Whenever a treating physician is in doubt on whether to perform DNAR or not, CPR should be performed as the default option. DNAR would apply to seriously ill patient where CPR would be inappropriate, nonbeneficial and likely to prolong the suffering of the patient in the best judgment of the physician.

Procedure as per ICMR Guidelines

a. Document to facilitate DNAR.
b. Give adequate opportunity, time and space to discuss with the patient and the family in private and facilitate the clear understanding of DNAR and its implications.
c. Team work and good communication are crucial.
d. Combined decision may be taken with the help of another physician or hospital administration.
e. DNAR forms should be available in the language understood by the patient / surrogate and should be signed, timed and dated.
f. Hospital administration should make efforts to sensitize their health care professionals on all issues related to DNAR.
g. In case of conflict of opinion, an independent 2nd opinion from a qualified medical practioner belonging to the relevant specialty may be sought by the treating physician/patient/surrogate in a timely manner.
h. Storage of DNAR forms: Completed, should be easily accessible to all the medical professionals to respond appropriately in the event to cardiorespiratory arrest of the patient concerned. All reports and forms should be archived for future reference.

Sedation in Seriously Ill Patients

When suffering cannot be managed at the end of life, sedation is an option. The literature shows a lack of consensus with regard to medication, doses and routs used

to induce sedation. Because of serious implications of terminal sedation, its implementation should follow guidelines based on compassion, consideration and trust.

Pain and Palliative Care

It should be initiated in seriously ill patients as per the Indian Association of Palliative Care (IAPC) guidelines.

CONCLUSION

A mature society will develop effective means for caring for its seriously ill members. Respect for the unique nature of each patient constitutes the essence of ethics in medicine. The challenge of ethics is to provide an intellectual and pragmatic frame work for pursuing the values of autonomy, beneficence and justice.

Chapter

2

Transfer of Sick Patients

Anjan Bhattacharya, Bichitravanu Sarkar, Bikramjit Das

INTRODUCTION

Law mandates that a sick patient, must be seen, stabilized and transferred in time by any health care establishment who see emergency patients or claims to be a day-night (24-hour) service. It is legally deemed as medical negligence, if health care facilities lack necessary gadgets in working order or qualified personnel to transfer in time.[1]

SUPREME COURT OF INDIA RULING

On being approached by the patient, if a medical profession person feels that standard of care that he could give is not really sufficient to save the life of the person, and some better assistance is necessary, it is the duty of the doctor to render all help that he can and also see that the person reaches the proper expert as early as possible.[2]

According to Consolidated Omnibus Budget Reconciliation Act (COBRA) of 1986: US congress, even transfer in a private car is legally acceptable, so long as the patient was adequately supported during the transfer. This was tested in India in the following case.

Case Study 1

Kamalesh Gupta v/s Dr Ajit Roy Chowdhary and others (State Commission of West Bengal SC Case No. 101/0/1997 decided on 28-6-2000). A sick patient with respiratory distress was transferred to a nursing home in the doctor's own car. All possible treatment was given to the patient, yet the patient expired. It was held that there was no negligence either on the party or doctor or nursing home.[1]

Even if a patient dies during the transfer, the law just requires that the matter be informed to the police, immaterial of death occurred whether under suspicious circumstances or if it was medicolegal case (MLC). A transferring doctor would need to certify the death.

Anxiety and fear amongst the health care fraternity largely comes out of ignorance. If one performs his or her best in the best interest of the patient, the law is actually there to protect the medical fraternity. On the other hand, defensive actions, disregarding patient's welfare, can land a professional in problems. The following case depicts it.

Case Study 2

Mr. Shakil Mohammed Vakil Khan vs Miss Perin Irani and others [The State Commission of Maharashtra, Bombay No. 219 of 1995 decided on 1.2.1999]. Here, Dr. Perin Irani performed LSCS and the anesthesiologist was informed that the blood of the patient was dark during the surgery. It subsequently required resuscitation and endotracheal (ET) intubation. The ET was removed later for fear of the patient biting the tube. The patient required ICCU admission, and was shifted to Breach Candy Hospital in an ambulance accompanied by the gynecologist, and the anesthesiologist followed the ambulance in his car. The opinion of the doctors in Breach Candy Hospital was that the patient had hypoxic encephalopathy and went into a vegetative state. Thus, a complaint was filed. The anesthesiologist claimed that it should be treated as medical mishap. It was held that the anesthesiologist did not accompany the patient in the ambulance, which he was professionally, morally and ethically required to do. The anesthesiologist was negligent in not providing oxygen during the surgery and above all did not accompany the patient in the ambulance. The anesthesiologist had to pay a compensation of Rs. 4,10,000.[1,3]

Therefore, the requirements are (1) to remain in a state of preparedness for transfer, (2) document well including transfer notes, (3) act for the best interest of the patient and document enough for a future independent assessor to be able to conclude so from you notes, and (4) do not fear the law. Abide by it. Write the death certificate, if you accompanied the patient, as appropriate and required by law. Inform police and cooperate with the law enforcing agencies. Please do not hurry and appear negligent in the process. State of preparedness mandates that the transferring professional is allowed the time to execute all legal obligations.

There are special circumstances, where the transfer issues pose special legal challenges as follows.

TRANSFER OF SICK PATIENT

Transportation of critically ill patient in a country like India can be quite a challenge unlike developed world. Some of the reasons are:

Poor road and traffic conditions	Disregard for traffic rules	Lack of civic sensibilities	Absence of established national and regional frameworks for patient transport

Medicolegal implications of such critical care transport are also intriguing because of this. Cases so far have only looked at nonspecialised transfers undertaken by the referring hospitals and deliberated only on aspects of medical negligence. Instead, what we need is clear rules and laws involving specialised and nonspecialised transfers of sick patient both from institutions and otherwise.[4,5]

In Supreme Court criminal Writ Petition No. **270** of **1988** it is held that "It is the duty of the medical men to render all the help to the patient which he could and also see that the person reaches the proper expert as early as possible".

In Writ Petition No. **796** of **1992** The Supreme Court held that before transfer three obligations are imposed:

Screening the patient	**Stabilising** the patient's condition	**Transfer** or **discharge** of the patient for better treatment

Some of the case examples are as follows:

Appeal No. 162 of 1991 The National Commission on the issue of transfer in haste observed	State Commissions of Kerala (No. 19 of 1990) and West Bengal (No.101/0/1997) held that	State Commission of Maharashtra (No. 219 of 1995)
"Hospitals should not avoid a terminally ill patient breathing his last while being under its care".	Transfer in a car is not negligent if all possible assistance were given to the patient while transportation.	Awarded compensation of Rs. 4,10,000 from the anesthesiologist for transporting the patient in an ambulance without oxygen

Indian Judiciary has not however considered other vital medicolegal issues that surround a critical care transport. Article 21 of the Indian constitution which guarantees Right to Life is the overarching constitutional provision under which medical services are provided. The doctrine of Primum non Nocere (do no harm) and patient's "best interest" must remain at the core of all interventions done to a patient at all times. Medical profession is governed by the doctrines of ethics such as beneficence, non-malfeasance and paternalism. Sections 88 and 92 of IPC can be invoked to cover many aspects of critical care transport.

This part of the chapter discusses certain common medicolegal issues that may arise during patient transport and the best practices which can minimise harm to the patient and shield medical professionals against litigations.

ALLEGATIONS OF NEGLIGENCE

Whenever there is a perception, from any quarter, that things have gone wrong, there may be allegations of negligence. In Kusum Sharma vs Batra Hospital Case (Civil Appeal No. 1385 of 2001), the Hon'ble Supreme Court has observed, "It is a matter of common knowledge that after happening of some unfortunate event, there is a marked tendency to look for a human factor to blame for an untoward event, a tendency which is closely linked with the desire to punish. Things have gone wrong and, therefore, somebody must be found to answer for it. A professional deserves total protection."The learned Supreme Court in its seminal judgement in the famous case of Jacob Matthew vs State of Punjab and Anr, 2005 has observed, "A mere deviation from normal professional practice is not necessarily evidence of negligence. Let it also be noted that a mere accident is not evidence of negligence. So, also an error of judgement on the part of a professional is not negligence per se. Higher the acuteness in emergency and higher the complication, more are the chances of error of judgement."The judgement further reads, "The essential components of negligence are three: 'duty', 'breach' and 'resulting damage'." In assessing breach/dereliction of duty, Hon'ble Supreme Court says, "The standard to be applied for judging, whether the person charged has been negligent or not, would be that of an ordinary competent person exercising ordinary skill in that profession. It is not possible for every professional to possess the highest level of expertise or skills in that branch which he practices. A highly skilled professional may be possessed of better qualities, but that cannot be made the basis or the yardstick for judging the performance of the professional

proceeded against on indictment of negligence. The test for determining medical negligence as laid down in Bolam's case [1957] 1 W.L.R. 582, 586 holds good in its applicability in India."To put in simple words, Bolam test matches against what a doctor of identical professional standing would have done in an identical situation. A failure to document the care of a patient thoroughly, particularly, if there is an untoward event, may seriously harm the team's defence!

DOCUMENTATION AND RECORD KEEPING

Documentation is of utmost importance at every step of patient care as the learned courts throughout the world have concurred time and again that "If it is not written down; it did not happen." Legal outcomes are not based on 'truth' but on 'proof' (Griffith, 2007), and only appropriate documentation serves as proof of interventions and communications during any part of patient care. It is important not to conceal facts to help insurance claims as this may go against the doctor in due course. It is also advisable to photocopy ECG and blood gas printouts as these tend to fade away over time. Pre-transfer family communication is best done with video-recording after obtaining consent from family for the same. A contemporaneous record of all the key events of the transfer should be made. This should start with the details of the initial telephone call requesting transfer and cover the time through to the handover to the receiving hospital staff, or the decision not to transfer. All communications, face to face or via telephone, should be documented. Independent or regional transport services, which are not based at the receiving intensive care unit, will need to keep their own copies of the transport record and also make copies, available at the point of handover to the receiving unit. These copies should be filed in the patient's hospital in-patient record and must be stored for the recommended statutory period.

ACCOUNTABILITY AND CLINICAL RESPONSIBILITY

When hospital is referring the patient to higher centre due to lack of in-house facilities, onus lies on referring doctor and the hospital as part of their duty of care to locate the most suitable PICU bed and arrange transport either with their own team or sending requisition to a specialised transport team either from the accepting hospital or a stand-alone service, depending on the critical condition of the patient and available resources at the referring hospital. For time critical transfers where waiting for transport team to arrive can cause delay in transfer leading to significant harm to the patient, as in cases of head injuries, neurosurgical emergencies, etc., transport must be arranged by the local team, preferably led by their anesthetist. The consultant in charge of the patient's care at the referring hospital will remain responsible for the care until the transfer team have received handover, assessed the patient and formally accepted the patient into their care. Thereafter, the responsibility for clinical care rests with the consultant in-charge of the transport team. The transfer team may recommend a management plan to be followed prior to their arrival. This would be considered expert advice. Where the advice is followed, the transfer team will take some responsibility for the consequences of their advice being followed. Where advice is not followed and a poor outcome occurs, it will be for the local team to explain why they took an alternative course.

DEATH DURING TRANSPORT

Any decision to move an unstable patient considered to be at a high risk of dying during transfer should involve an open and thorough discussion between the medical teams (referring and transferring) and the parents regarding the appropriateness of moving the patient and parents have the right to decline transfer where appropriate. The risks of any critical care transfer should be clearly explained to parents and the discussions and the decision taken must be thoroughly documented in the clinical notes. If any person disagrees with the chosen course this should be documented, together with their reasons for disagreeing where possible. Should the patient acutely deteriorate during transfer, it is advisable to divert to the nearest hospital for stablisation. Should the patient die during transfer, the time of death and the exact location of the death must be documented. Law requires the matter to be informed to the police, only if the death is under suspicious circumstances or if it is a medicolegal patient, but it may be a good practice to intimate the police anyway. Issuing of Death Certificate for death during transfer will depend on the transfering doctor's decision. The situation is no different from one where a newly admitted patient dies in a hospital. If from the clinical history received from the referring team and the family and from the examination findings, the doctor is able to identify a natural cause of death, the transferring doctor should issue the death certificate, but if he is not satisfied about the patient's circumstances and is unclear about the exact cause of death, he should not issue death certificate but refer the case for autopsy.

TRANSFER OF SICK NEONATES[6,7]

This topic will focus on the following:

1. Special medicolegal aspects pertaining to transporting a sick newborn.
2. How we can ensure a safe transport from the medicolegal point under given current scenario?
3. What further needs to be done on this aspect?

Introduction

The state of neonatal transfer is quite grim in our country and this is reflected in the high neonatal mortality rate. The key causes are lack of *in utero* transfer to higher centre, lack of trained proper transport teams, not transporting a neonate to appropriate centre as per level of care while stable, transporting a neonate usually after deterioration without adequate stabilization. As expected, the laws governing transporting a sick newborn are equally lacking in our country.[8,9]

MEDICOLEGAL ASPECTS PERTAINING TO TRANSPORT OF A SICK NEWBORN AND THEIR CURRENT SCENARIO IN OUR COUNTRY[10]

The following aspects involved in transport have an important medicolegal side to them besides the clinical part. It is given in Table 2.1.

Table 2.1

Transport component	*Expectation*	*Current scenario*	*Way ahead*	*Medicolegal implication*
Transport team:				
1. Lead medical personnel and lead nurse	Trained in advanced NRP and at least 6 months training in level 3 NICU and neonatal transport, experienced in transporting critical neonates	Most transport are either not or inadequately supervised by untrained personnel, not officially transport trained, very less experience	Increase advanced and basic NRP training of fellows and nurses Establish national neonatal transport teams, extend training and data sharing	
2. Additional medical staff (doctors and nurses)	Trained in basic NRP, 6 months experience of working in level 2 NICU, having accompanied few neonatal transports			
3. Ambulance facilities	Incubator, ventilator, infusion pumps, resuscitation and other necessary drugs, oxygen, lighting, air conditioner, battery backup	National ambulance service vehicles are grossly unequipped. Private hospital transport vehicles are better equipped although not universally	Designate neonatal transport ambulances and upgrade as per norms	Can amount to medical negligence under Consumer Protection Act
4. Technician	Thoroughly trained in use of equipment and their troubleshooting	Relatively well as compared to other components of transport team	Train technicians in basic NRP	
5. Driver	Well knowledge of ambulance and terrain	Usually up to the mark	Train technicians in basic NRP	
Informed consent	Elaboration of: Clinical condition and working diagnosis Need for transport Hospital where transport is being done to distance and time of travel Chances of on road complications and plan	Current consent forms are not standardised, do not provide all the necessary information, do not have provision for actions in case of on road emergency, often signed by patient attendants in hurry without proper reading	Standardised consent forms detailing all aspects of transport Local language forms Well communicated and understood by family members Sign by father or legal guardian as mother and patient	Can amount to medical negligence under Consumer Protection Act

(Contd.)

Transport component	*Expectation*	*Current scenario*	*Way ahead*	*Medicolegal implication*
	in such cases Cost of transport Costs of treatment in referral hospital Family relatives to accompany transport team		(baby) are unavailable	.
On road emergencies/accidents				
Equipment failures	Alternative backups (e.g. if incubator fails, additional hot water bags for maintaining temperature)	Currently such backups and scenario management is lacking as these are usually achieved through stimulation training and experience	Establishment of unit guidelines for patient care during transport including management of emergencies	May lead to loss of life of patient or grievous damage and may inculcate medical negligence or compensations if emergency not managed to the best of teams ability
Predicted emergencies	Management as per guidelines (e.g. tube displacement, cardiac arrest)		Stimulation training of personnel involved in transport	
Unpredicted emergencies	Utilisation of presence of mind and available resources (e.g. accident, bad weather)	Usually followed	Ensure proper disposal of deceased and handing of death certificate	
On road death	Body transported to nearest higher centre, casualty admission does and provision of death certificate by transport team			

WAY FORWARD FOR OUR COUNTRY

A lot needs to be done in our country first in training of medical personnel and staff in transport, establishment of transport guidelines and protocols, stimulation trainings, certified courses, dedicated patient transport ambulances, etc. Simultaneously, a lot needs to be done on the legal front to provide protection to medical fraternity from various complications arising from transport. In the absence of these, our country continues to undertake poor quality transport which continues to risk patients and result in higher deaths.

REFERENCES

1. K. Shivakumar. Transportation of the patient: Legal binding of anaesthesiologist. *J of Med.leg Article* 2010; 54(4):367–68.
2. Shenoy GN, Shenoy GG. Anesthesiology and Law of Medical Negligence. Bombay: Ritanjan Publications; 2002; p. 212–4.
3. Singh J. Medical negligence and compensation. Jaipur: Bharat Law Publications; 2007: p. 105, Para 6–15.
4. Transport of a sick neonate. NNF clinical practice guidelines. Saluja S, Malviya M, Garg P.
5. Agrawal S, Banot A, Sangar K. Neonatal care and Transport among the Urban Poor: Challenges and Options. *J of Neonatology* 2005; 19:347–352.
6. Cornette L. Transporting the sick patient. *Current Pediatr* 2004;14: 20–25.
7. Kulshrestha A, Singh J. Inter-hospital and intra-hospital patient transfer: Recent concepts. *Indian J Anaesth* 2016; 60:451–7.
8. Pandit MS, Pandit S. Medical negligence: Coverage of the profession, duties, ethics, case law, and enlightened defense: A legal perspective. *Indian J Urol* 2009; 25: 372–378.
9. Nandimath OV. Consent and medical treatment: The legal paradigm in India. *Indian J Urol.* 2009; 25: 343–347.
10. Roy MP, Gupta R, Sehgal R. Neonatal transport in India: From public health perspective. *Med J DY Patil Univ* 2016;9: 566–69.

Chapter
3

On Table Death (Operation Theatre)

Girish Kumthekar

On table death is something no surgeon would dream of having in his own establishment. It is a frequent though not routine incidence in a general hospital, government hospital or a tertiary referral centre but to have it in a small individual setup is a nightmare. On table deaths are more common with obstetricians and super-specialty surgeries like onco-surgery, cardiac surgery or transplant surgeries. Table deaths in case of a very complicated, high risk cases or super-specialty cases are explained to the relatives and are anticipated to certain extent and hence are accepted by relatives without much of hassles. However, table deaths in obstetrics are a different story. Such deaths are a bolt from the blue and is a sudden event which upsets not only relatives but also the treating consultant. Particularly in obstetrics when a happy expectant mother walks into the operation theatre and her human remains are brought out on a gurney after few hours is something dreadful and unacceptable.

All the obstetricians, barring a few exceptions, experience or witness on table death, at least once in their professional career. Anesthetists are the next professionals who witness this unexpected event more often than obstetricians while working with other specialties such as orthopedics or general surgery. This is a very unexpected event and even if anticipated creates some problems and the concerned consultants may have to face legal actions. For this reason alone, all doctors, hospital owners in general and operating specialties in particular should be ready to face on table death.

CAUSES

This chapter will not deal with causes of table death as that is not the purpose of this book. The cause could be shocked of any type hemorrhagic, neurogenic, etc. or it could be embolism, intracranial or cardiac event. It can also be an anesthetic event or wrong drug administration. Anaphylaxis is also one of the causes of table death. Apart from various causes the fact remains a fact that table death has occurred and we have to deal with it medically, socially and legally.

PRE-EMPTIVE MEASURES

Informed written consent is a must before taking the patient inside the OT. It must be signed by the patient and preferably signed by two witnesses; one from the relatives and if possible one attendant or a person not related directly to the patient (technically one witness is enough). If patient is not in a condition to give consent or is minor, the

next of the kin or legal guardian must sign the consent form. Proper counselling regarding the nature of operation, type of anesthesia to be administered, possible common complications, inherent dangers and complications of any surgery must be explained to the patient and relatives. This all conversation must be in local language as understood by the patient and relatives and must be documented by putting a note in the IPD case paper or consent paper that such conversation has taken place. If possible, video-recording with voice is the most effective and authenticated documentation.

SITUATIONAL ACTION

To deal comfortably with table death situation one must have a fully equipped OT which is plush with all paraphernalia of surgery apart from various pieces of equipment in working condition. All the drugs must be available in adequate quantities. Oxygen supply should be adequate and emergency drug tray must be handy. All required resuscitative pieces of equipment including defibrillator should be available in OT or at some easily accessible place in the hospital. The recommendation is not to keep anything locked inside the OT. Checklists of common actions in the OT are very helpful and reduce the mistakes significantly. It is imperative on the part of anesthetist to see that the necessary armamentarium is maintained and in working condition and he reserves right to refuse anesthesia if deficiencies are noticed. Only in case of dire emergency or life-saving measurements you can overlook certain deficiencies but not otherwise. It is the duty of the hospital owner or administrator to see that all the pieces of equipment are maintained and are in working condition.

BREAKING THE NEWS

Breaking the bad news is to be handled very carefully. Each case deserves to be handled by its merits. The various ways in which bad news can be broken are:

- **Immediate:** Sometimes it is necessary to declare death immediately. This method has both its pros and cons. It can bring around immediate violent reaction as stated below. Sometimes immediate declaration reflects transparency and relatives do not grumble much. This all is circumstantial and doctor has to use his utmost management skills.
- **After cover-up:** Cover-up does not mean manipulations. The procedure of keeping the patient on artificial means and pretending to be alive does not work in true sense. It is a common practice to keep the patient on ventilator and breaking the news slowly after intensifying the situations step by step. The problem here is many of the bystanders and witnessing relatives happen to have realized that the things have gone wrong. They feel that extension and pretentions are a drama for other causes and then they retaliate.
- **Conveniently by another person may be staff nurse or servants:** This probably is the simplest way but sometimes agitated relatives are not happy to listen to subordinates and they want a direct interaction with doctor.
- **After asking all the responsible relatives to gather and then explain in presence of colleagues:** This probably is the safest way to break the news. This should be done preferable in your own consulting room. Remember that your consulting room is the most comfortable place for such things. You happen to be the most

powerful in your own consulting room. Sit comfortable on your chair ask your colleagues to sit by your side and ask the relative to sit across the table. This creates a wall of power between you and the relatives and keeps you safe. Never go directly into the mob and start giving explanation, this may precipitate direct manhandling.

The reaction of the relatives to such sudden death is:

- Anger and anguish
- Immediate explanation—relatives demand immediate explanation on the spot. This is not possible for the doctors and is to be avoided. This, however increases the agitation and suspicion in the minds of relatives aggravates.
- Financial waiver and immediate compensation: It is not helpful as the things do not stop there. In fact, the demands get escalating as the time passes.
- Immediate police action: This usually is demanded by so-called leaders of that particular area or community. They pressurize the police to register crime and insist on immediate arrest of the doctor. However, with the recent amendments in the CrPC, immediate arrest of doctors is not possible in case of death caused during the course of treatment. The Supreme Court has also given our community a lot of reprieve in its latest judgments. You will find these remedies and judgments elsewhere in this book.
- Verbal or physical abuse and immediate retaliation with destruction of property This is the worst thing that can happen and doctors are really afraid of this situation.

Immediate reaction of the treating doctor in such case could be:

- Run away from the situation—never do this. Remember back door is always being watched by the people who gather there. It will only make the things worse.
- Immediate cover up and unnecessary explanations—this should be avoided. The doctors should not face multiple relatives immediately and start giving explanations. The paramedical staff should also be told to keep shut so as to avoid different versions. One should keep his nerves, take a break for few minutes after exhaustive resuscitative efforts have failed, organize the things in OT, pool all the empty vials used during resuscitative measures, take a look at the papers and take them into your custody. (This is to prevent unauthorized copying of the papers without knowledge of anybody.) Later on, one should call only the responsible relatives separately into the counseling or consulting room and explain the situation.
- Settle the matter as early as possible by political or financial means: This is the most common practice adopted by doctors but this should be avoided under any circumstances as this sets precedence to future mischief mongers and political leaders. However, sometimes it becomes imperative on the part of doctors to call a close politician particularly of that community and take his help. Please remember that in such situations the politician is going to demand his pound of flesh later on. At times the politician may play a duplicitous role and harass both parties.
- Fight the situation overconfidently: This must be avoided and even your body language should not be as such. Being too confident is as damaging as being too defensive. Dismissing the relatives and not giving proper explanation further aggravates the situation.

- Retaliate the abuse by abusive language: This possibly is the worst thing a doctor should do. The dictum is the relatives may abuse in any language, you cannot reply in the same language as your abusive language shall be capitalized immediately and more and more abuses start getting hurled at you. This also increases the tension in the atmosphere and temperatures start running very high.

What relatives do in such situation?

- Manhandle the doctor, destruction of the property and hospital equipment
- Threatening the doctor
- Lodge a criminal complaint
- Insist on arrest of the doctor
- Invite the media to spread the news
- Demand for money.

These situations are self-explanatory and we have to deal with them instinctively.

What doctor should do?

- Call the colleagues and seniors for help: This probably works more than anything else. Prepare a task force on the platform of organizations like IMA, or specialty by medicolegal cells society. All seniors, colleagues from all specialties should rush to the troubled spot at the shortest notice. This diffuses the situation very fast. There are many persons in the mob who happen to be patient of one or the other doctor from task force and such senior consultant can diffuse the situation and mediate on behalf of the treating doctor.
- If the situation is going out of hand, call the police.
- No repeated explanatory statements to be made in front of different people who demand explanation. This leads to variations in explanations and confusion in the minds of relatives which makes them more suspicious.
- Involve only the responsible persons from the aggrieved family.
- Be a patient listener to the allegations and abuses. You just cannot retaliate by equally abusive language. Even a single abusive word uttered by you is capitalized by the already agitated relatives and this escalates the situation further.
- Discuss the problem with colleagues who have come in to help and prepare a logical sequence of events.
- Take time to prepare the case paper and put proper notes.
- Cooperate with the legal arm
- In case cause of death can be given, certify the death
- Ideally medicolegal postmortem is a must in OT death. The reason is, OT is a restricted place with a limited access. All the measures of saving the patient are done inside the four walls which always arouse doubts in the minds of relatives.

DOCUMENTATION

The maxim, ' ***Good documentation is a good defence, poor documentation is a poor defence and no documentation is no defence***' is heard by almost everybody and is Gospel's truth. As already said, one has to compose himself, talk to the paramedics, anesthetist and the colleagues who have come to help you. Prepare a sequence of

events and document everything that has been done during the course of treatment and resuscitative measure. Put the papers sequentially and keep them in your safe custody not to be copied unauthorizedly. Sometimes the police demand the papers immediately which you can politely refuse because you have full 72 hours to prepare the documents and then hand over the copies to the legal arm. There could be frictions with police at this stage but you are protected by law and defer handing over the papers after some time. All the ingredients of the documents which include IPD paper, consent, surgical notes, anesthesia notes, nursing notes, TPR charts, investigation reports should form a part of the file and should be legible and in sequence. You will find more about documentation elsewhere in this book.

MOB HANDLING

Mob handling is a topic by itself and shall be dealt with in other chapters in this book. However, please remember that mob handling is a very skilled job. As already said, one should not go out and face mob bravely. You should always interact with a small delegation from the mob along with relatives. You must call some of them towards you. This plays a psychological game of creating a commanding situation in front of the mob. The leaders of the mob whom you give importance, themselves will see to it that the people become quiet. If the mob is getting violent and the situation is going out of hand it is best to call the police and protect yourselves and your property. In fact, one should always take a precaution to inform nearest police station about the necessity of protection.

DEATH CERTIFICATE

There is a lot of confusion amongst doctors about issuing death certificate. If you are sure of the cause of death, you can safely issue a death certificate in the government prescribed format and avoid postmortem examination. In case there is a slightest doubt in your and minds of relatives it always safe to get done postmortem examination. If postmortem is really required and relative are refusing it, it is best to inform the police, register MLC and hand over the body to police for further compliance.

CONCLUSION AND TAKE-HOME MESSAGE

- Every surgeon/hospital owner must be ready for an unexpected on table death at least once in life time.
- On table death is preliminarily treated as a death due to accident and attracts Section 304A of IPC.
- One should not try to be heroic and go overboard to handle cases which are beyond the capacity of your establishment and your expertise.
- Basic minimum requirements in the establishment, needed for your specialty and competency must be fulfilled.
- Take a proper informed written consent after proper counselling and all possible eventualities pertaining to the disease and case. It is not necessary to tell all remote and rare complications but most common complications must be explained in a simple language understood by patient and relative.

- In case of event do not hesitate to call colleagues and seniors for help and be honest with them so that they can understand the situation.
- Do not hesitate to call police if the situation demands it.
- In case of slightest doubts, do not issue death certificate and arrange for post-mortem examination. It is for your own safety.
- If the investigations and clinical course are not corroborating with the cause of death, never issue a death certificate.
- Documentation of all events is absolutely essential and it saves you in the courts of law. Consult with your colleagues and if possible, with a medicolegal consultant while putting the documents in order and before giving a copy to the law agency of relative. Changes done later on will not be accepted by courts.
- Do not try to shift already dead patient to tertiary centre just to avoid blot on your hospital. Remember people are watching you and your pretentions can be easily exposed which escalate the situation from bad to worse.
- Ultimately use all your experience, management skill, expertise, help from colleagues, etc. to diffuse the situation.

I have not dealt with further legal formalities and actions taken by law agencies as it will be covered in some other chapters in this book.

Chapter

4

Unexpected Stillbirth and Intrauterine Death

Sai Kiran

INTRODUCTION

Few obstetric complications are as emotionally devastating as still birth both for the patients and clinicians. Still birth is defined as *in utero* fetal death at 25 weeks of gestation or later. In developing countries like India, there is a high incidence of still births. Currently even though litigations are not very common after a stillbirth, yet all medical professionals involved in the obstetric care should ensure that preventable still births are avoided.[1]

Despite the magnitude of the problem, relatively little attention has been focused on stillbirth during the past decades. Accordingly, many clinicians are uncertain as to the optimal evaluation of stillborn infants. In this chapter, we will review current recommendations for the evaluation of stillborn infants to avoid medicolegal pitfalls.[2]

IMMEDIATE STEPS IN THE MANAGEMENT[3]

Stillbirth is a baby delivered with no signs of life and known to have died after 24 completed weeks of pregnancy. Intrauterine fetal death (IUFD) refers to the babies with no signs of life *in utero*.

Diagnosing IUFD

Optimal method of diagnosing IUFD should be real-time ultrasonography augmented with color Doppler of the fetal heart and umbilical cord and collapse of the fetal skull with overlapping bones, hydrops, or maceration resulting in unrecognizable fetal mass. Intra-fetal gas (within the heart, blood vessels and joints) is another feature associated with IUFD that might limit the quality of real-time images. Auscultation and cardiotocography should not be used to investigate suspected IUFD. A second opinion should be obtained whenever practically possible. Mothers should be counselled for the possibility of passive fetal movement. If the mother reports passive fetal movement after the scan to diagnose IUFD, a repeat scan should be offered.

Disclosing IUFD to the Patient

If the woman is unaccompanied, an immediate offer should be made to call her partner, relatives, or friends. Discussions should aim to support maternal/parental choice.

Couple should be offered written information to supplement discussions. Empathetic techniques, which can enhance recovery, can be learned, and retained as a skill by the clinicians. In a stillbirth or IUFD it is preferred to have continuity of same caregiver and supplementary written information.

Managing Labor and Birth Process in IUFD

Mode of delivery should consider the mother's preferences as well as her medical condition and previous intrapartum history. Women should be strongly advised to take immediate steps towards delivery if there is sepsis, pre-eclampsia, placental abruption or membrane rupture, but a more flexible approach can be discussed if these factors are not present. Vaginal birth is the recommended mode of delivery for most women, but cesarean birth will need to be considered with some. A discussion of the safety and benefits of induction of labor should be undertaken by a consultant obstetrician with the patient and her family members and an informed consent needs to be obtained.

Facilities Required for the Stillbirth Labor

Women should be advised to labor in an environment that provides appropriate facilities for emergency care according to their individual circumstances.

In a labor ward room, pay special heed to emotional and practical needs of the women without compromising safety. This can include a double bed for her partner or other companion to share, away from the sounds of other women and babies. Care in labor should be given by an experienced midwife. Adequate analgesia and asepsis should be maintained during the labor. Suppression of lactation is of psychological importance for some women following IUFD.

Health care personal must be alert to the fact that mothers, partners and children are all at risk of prolonged severe psychological reactions including post-traumatic stress disorder and that their reactions might be very different. Counselling should be offered to all women and their partners.

Investigating the Cause of Late IUFD[4]

Clinical assessment and laboratory tests should be aimed to determine maternal health (including coagulopathy) and to determine the cause of stillbirth, the chance of recurrence and further pregnancy complications. A detailed history of events during pregnancy and clinical examination for pre-eclampsia, chorioamnionitis and placental abruption shall be recorded. There is also a moderate risk of maternal disseminated intravascular coagulation (DIC)—10–30% within 4 weeks after the late trimester IUFD. This can be tested for by clotting studies, blood platelet count and fibrinogen measurement. Documentation of IUFD should follow an established classification system such as the relevant condition at death (ReCoDe) system, or systems that capture multiple and/or sequential contributing factors, such as Tulip, Perinatal Society of Australia and New Zealand–Perinatal Death Classification (PSANZ-PDC) or causes of death and associated conditions (CODAC). An objective documentation of the maternal and fetal details along with the required investigations in case of a stillbirth

is shown in Fig. 4.1. Commonly associated antepartum conditions include congenital malformation, congenital fetal infection, antepartum hemorrhage, pre-eclampsia and maternal disease such as uncontrolled diabetes mellitus. The common causes of intrapartum death include placental abruption, maternal and fetal infection, cord prolapse, idiopathic hypoxia—acidosis and uterine rupture.

Parents should be advised that no specific cause is found in almost half of stillbirths and that when a cause is found it can crucially influence care in a future pregnancy. Patients should be made aware about the nature of tests and need for a correlation between blood tests and postmortem examination of the fetus. Further tests might be indicated following the results of the post-placental examination. Systems that use customized weight charts and capture multiple contributing factors should be used to categorize late IUFDs.

PART 1 – STILLBIRTH INVESTIGATION AT BIRTH

A. Placenta and Cord - collect placenta tissue (unfixed) for:

- ☐ Karyotype (Sodium Heparin Vaccutainer)
- ☐ Culture (fresh or in sterile saline)
- ☐ Placenta and cord to histopathology

B. Autopsy

- ☐ Full consent
- ☐ Limited consent (specify)
- ☐ X-rays (ANATOMICAL POSITION)
- ☐ Clinical photographs
- ☐ Others (specify) _____
- ☐ Declined
- ☐ Not requested

C. Maternal Investigations – at the time of diagnosis or after birth

- ☐ CBC, Platelet count
- ☐ PT, aPTT, Plasma fibrinogen
- ☐ Blood group and Rh type, antibody screen
- ☐ Kleihauer-Betke
- ☐ Syphilis serology, parvovirus, CMV, rubella & toxoplasmosis
- ☐ HBA1C
- ☐ Blood Sugars
- ☐ TSH
- ☐ Anticardiolipin antibodies, lupus anticoagulant
- ☐ TORCH
- ☐ Other: (Specify) _____

D. Documentation to pathologist

- ☐ Placenta form filled up
- ☐ Autopsy consent form

E. Follow-up arrangements

- ☐ Thrombophilia work-up
- ☐ Results reviewed and discussed with parent by: (name and title)

_____

_____

Appointment date (yyyy/mm/dd)

Fig. 4.1: Case record form in a stillbirth (*contd.*)

Gestational age: _____

Sex of the baby: ☐ Male ☐ Female ☐ Unknown ☐ Ambiguous

Weight in gram: _____

Circumference (cm): Head _____ Chest _____ Abdomen _____

Length (cm): Crown-heel _____ Crown-rump _____ Foot _____

		Normal	Abnormal	
1	General Appearance	☐	☐ Fresh stillbirth	☐ Macerated + ++ +++ ☐ Edema ☐ Hydrops
2	Skin	☐	☐ Meconium Stained ☐ Petechiae	☐ Jaundice ☐ Bruising ☐ Peeling ☐ Birth marks
3	Head	☐	☐ Hydrocephalic ☐ Neural tube defect, (specify)	☐ Collapsed ☐ Shape of skull
4	Scalp	☐	☐ Defect	
5	Eyes	☐	☐ Spacing ☐ Standing	☐ Narrow ☐ Wide ☐ Opaque ☐ Cataracts ☐ Sunken ☐ Prominent ☐ Up Down ☐ Eyelid fused
6	Nose	☐	☐ Flat bridge	☐ Asymmetric
7	Nostrils	☐	☐ Obstructed	☐ Single nostril
8	Ears	☐	☐ Low set ☐ Abn form	☐ Periautricular tags / pits ☐ Posterior rotation
9	Mouth	☐	☐ Small ☐ Cleft lip	☐ Large ☐ Cleft palate
10	Mandible	☐	☐ Micrognathia	☐ Asymmetric
11	Neck	☐	☐ Short	☐ Excess skin ☐ Cystic mass
12	Chest	☐	☐ Asymmetric ☐ Barrelled	☐ Small ☐ Nipples wide spread ☐ Constricted ☐ Sternal defects
13	Abdomen	☐	☐ Flattened	☐ Distended ☐ Omphalocele ☐ Wall defect ☐ Gastroschsis
14	Cord	☐	☐ Vessels	☐ Cord Constriction ☐ True knot
15	Back	☐	☐ Sacral dimple ☐ Scoliosis	☐ Neural tube defect _____ ☐ Kyphosis
16	Arms	☐	☐ Short ☐ Long	☐ Abnormal muscle development ☐ Contractures ☐ Abnormal positioning ☐ Absent
17	Hands	☐	☐ Abnormal creases ☐ Missing digits ☐ Abnormal positioning	☐ Webbed fingers ☐ Abnormal nails ☐ Extra digits _____
18	Legs	☐	☐ Short ☐ Long	☐ Abnormal muscle development ☐ Contractures ☐ Abnormal positioning ☐ Absent
19	Feet	☐	☐ Club foot ☐ Extra toes ☐ Webbed toes	☐ Missing toes_____ ☐ Abnormal nails ☐ Abnormal positioning
20	Stature	☐	☐ Proportionate	☐ Disproportionate a) Span_____ b) LS _____ c) US _____
21	Genital-Rectal	☐	☐ Hypospadias ☐ Ambiguous	☐ Undescended testes ☐ Imperforates anus
22	Others	☐		

Impression: _____

Signature of Docotor : _____ **Name :** _____

(*Contd.*) **Fig. 4.1:** Case record form in a stillbirth

Gender Identification of the Fetus

Parents can be advised before birth about the potential difficulty in sexing the baby, when appropriate. Two experienced health care practitioners (midwives, obstetricians, neonatologists or pathologists) should inspect the baby when examining the external genitalia of extremely preterm, severely macerated or grossly hydropic infants. If there is any difficulty or doubt, rapid karyotyping should be offered using quantitative fluorescent polymerase chain reaction (QF-PCR) or fluorescence *in situ* hybridization (FISH).

Pathological Autopsy of the Stillborn and Placental Examination

Parents should be offered full postmortem examination to help explain the cause of an IUFD. A postmortem examination provides more information than other (less invasive) tests and this can sometimes be crucial to the management of future pregnancy.

Parents' individual cultural and religious beliefs must be respected. Written consent must be obtained for any invasive procedure on the baby including tissues taken for genetic analysis. Consent should be sought or directly supervised by an obstetrician or pediatrician explaining the nature of perinatal postmortem, including retention of any tissues for clinical investigation, research, and teaching.

Parents should be offered a description of what happens during the procedure and the likely appearance of the baby afterwards. This should include information on how the baby is treated with dignity and any arrangements for transport. Discussions should be supplemented by the offer of a leaflet. Postmortem examination should include external examination with birth weight, histology of relevant tissues and skeletal X-rays. Pathological examination of the cord, membranes and placenta should be recommended whether postmortem examination of the baby is requested. The examination should be undertaken by a specialist perinatal pathologist.

Parents who decline full postmortem might be offered a limited examination and less invasive methods such as needle biopsies can be offered, but these are much less informative and less reliable than the conventional postmortem but this is not straightforward and should be discussed with a perinatal pathologist before being offered.

Preventable Stillbirth

Major cause of litigation in the perinatal period can be prevented by minimizing preventable stillbirth and thereby other associated problems like birth injuries and asphyxia. This can be achieved by detection and management of fetal growth restriction, fetal surveillance and if needed, assisted vaginal delivery and cesarean section, post-term labor induction.

LEGAL PROVISIONS AND LAWS APPLICABLE

- The current law on stillbirth registration is set out in the Registration Births and Deaths Act, 1969. The legal definition of stillbirth is "any child expelled or issued forth from its mother after the 24th week of pregnancy that did not breathe or show any other signs of life".[5]

- Stillbirth must be medically certified by a fully registered doctor present at the time of birth or examined the baby immediately after birth.
- Police should be contacted if there is suspicion of deliberate action to cause stillbirth.
- Doctor attending the stillbirth is required to issue a medical certificate of stillbirth that enables the birth to be registered. The cause and sequence of medical events leading to the IUFD should be given in as much detail as possible. Nonspecific terms such as anoxia, prematurity and so on should be avoided. Certification should not be delayed for the results of the postmortem.
- Stillbirth must be registered 21 days of the birth. This responsibility is with the designated health professional of the hospital.
- The legal responsibility for the child's body rests with the parents but can be delegated to hospital services. Parents should be allowed to choose freely about attendance at a funeral service. A leaflet about the options should be available.
- Documentation of the case record should be appropriate with written informed consent of the discussion with the couple regarding IUFD disclosure and regarding labor plan. Fetal postmortem and placental examination—nature, benefits and choice, expectations for physical recovery, lactation suppression, registering the birth including addresses of local authority site, guidance on fertility and contraception and plan for the follow-up.

FUTURE AMENDMENTS IN LAW

Any future amendment in the law must take into consideration the provision for all children who died of sudden infant death syndrome or stillborn after a gestational age of 25 weeks are to be autopsied. Obtain the parental consent for tissue collection and storing and to manage maternal–fetal data. By law the health authorities need to identify the regional institutes, which can devise the autopsy protocols, and that the findings of the investigations are to be collected in the national data bank that will send the information to the doctors and other stakeholders in a duly anonymous form, regarding prevention and sensitization campaigns and programs of continuous information in medicine, aimed at obstetricians, gynecologists, pediatricians, neonatologists, pathologists, histologists, general physicians, and nursing staff.

KEY MESSAGES

- Ensuring skilled ultrasound diagnosis should be the basis of the late IUFD.
- Proper fetal surveillance like partogram and cardiotocograph.
- Proper documentation of the informed discussions with parents about diagnosis of IUFD.
- Obtaining informed consent from the parents on the fetal postmortem examination.
- Ensuring safety in induction of labor and monitoring.
- Proper classification of stillbirth (like ReCode).
- Facilitating every stillbirth with the appropriate authority under the Birth and Registration Act, 1969.

REFERENCES

1. Bernis L de, Kinney MV, Stones W, Hoope-Bender P ten, Vivio D, Leisher SH, et al. Stillbirths: ending preventable deaths by 2030. The Lancet. 2016 Feb 13;387(10019):703–16.
2. Available from https://www.fogsi.org/wp-content/uploads/fogsi-focus/FOGSI-FOCUS-Medicolegal-2018.pdf. Accessed on 10th August, 2020.
3. Silver RM, Varner MW, Reddy U, Goldenberg R, Pinar H, Conway D, et al. Work-up of stillbirth: a review of the evidence. *Am J Obstet Gynecol* 2007 May 1;196(5):433–44.
4. Late Intrauterine Fetal Death and Stillbirth (Green-top Guideline No. 55). Royal College of Obstetricians and amp; Gynaecologists. [cited 2020 Mar 30]. Available from: https://www.rcog.org.uk/en/guidelines-research-services/guidelines/gtg55/. Accessed on 10th August, 2020.
5. The Registration of Births and Deaths Act, 1969. [cited 2020 Mar 30]. Available from: https://indiankanoon.org/doc/1636244/. Accessed on 10th August, 2020.

Chapter
5

Brought Dead Patient

Padmakumar K

INTRODUCTION

Patient found to be already clinically *dead* upon the *arrival* at hospital is a common situation a medical practitioner faces during his practice. Here the medical practitioner has a legal and ethical duty to ascertain and declare death. In addition to this, medical practitioner is duty bound to certify the cause of death if the manner is natural and inform the legal authority if it is unnatural.

In India as per provisions of Section 10(3) of Registration of Births and Deaths Act 1969, every medical practitioner is duty bound to issue a death certificate in cases where he has attended to a person during his last illness and where he is satisfied that the death was due to natural causes.[1] The medical practitioner cannot charge any fee for issuing the same and the act clearly says that it shall be issued only when the medical practitioner is satisfied that the death was due to natural causes. This legal duty is easy to perform when the person is under treatment for a particular disease and dies when under care. If a patient dies while undergoing treatment at his residence, the doctor may certify death, provided he has seen the patient within twenty four hours preceding death.

PROCEDURE TO BE FOLLOWED

In all cases of brought dead first and foremost step is documentation, after ascertaining death. Record the details in death register/brought dead register. Second duty is collection of history and third is a complete examination of body. If history/examination suggests any of the following situations, medical practitioner is duty bound to intimate the nearest/jurisdictional police station about the death after registering it as a medicolegal case. The situations are:

a. Death by accident, suicide or homicide
b. Death caused by animals or snake bite
c. Allegation of negligence
d. Suspicious of death of a married woman within seven years of marriage.

These are the situations where a medical practitioner can act without any confusion but difficulty arises when a person is brought dead to the hospital or dying in the hospital after attending and before making a diagnosis.[2] The doctor is unable to certify the cause of death since he has not attended the person as a patient or has not diagnosed

his illness. It is ideal to report this matter to the nearest/jurisdictional police station. If he does not comply with this and releases the dead body for disposal and later it turns out to be an unnatural death, the medical practitioner is even liable for omission to give information of an offence or causing disappearance of evidence of an offence.[3] Hence, it is advised not to issue a death certificate in any of the following situations:

1. Where the medical practitioner is called to see a person who is brought dead and whom he had never examined before?
2. When a medical practitioner is not sure of the cause of death of a person who has been under his treatment or when he has some suspicion as regards to cause of death?
3. Where there is a slightest suspicion of violence even in presence of serious natural disease?

CASE LAWS

In Monica Singla and others v/s Tej Bhan and others, the honourable court directed that issue death certificate only when absolutely sure about the cause of death.[4] Otherwise it could be held as negligence and could also invite criminal prosecution. In another case (Rajesh v/s Dr. Lokram Laxmandas Bajaj and others) the court held that do not issue death certificate merely because the medical practitioner has attended the patient before death and do so only if the medical practitioner is sure about the cause of death.[5]

CONCLUSION

Death certificate shall be issued only if the manner of death is natural and cause of death is known beyond all doubts.

REFERENCES

1. Section 10(3) of Registration of Births and Deaths Act, 1969.
2. Umadethan B. Principles and Practise of Forensic Medicine In: Death, CBS Publishers and Distributors Private Ltd, New Delhi; Second Edition, 2016, pp 6–7.
3. Dogra TD, Rudra Abhijit. Lyons's Medical Jurisprudence and Toxicology, In Chapter XVII Medicolegal Aspects of Death, Law House : Delhi 11th Edition, 2016, pp 229–231.
4. Monica Singla and others v/s Tej Bhan and others 2015 (4) CPR 540, 2016 (1) CPJ 588, 2016 (3) ALD 24.
5. Rajesh v/s Dr. Lokram Laxmandas Bajaj and others; 06/01/2005 in Case No. CC/308/2002).

Chapter

6

Brain Death: Medicolegal Issues

Sheikh Minhaj Ahmed, Anil Lohar

INTRODUCTION

Cessation of cardiorespiratory function has been historically defined as death. The declaration of a person to be brain dead has always been a topic of debate and an unresolved problem for a long time. The concept of brain death was introduced into clinical practice, more than 50 years ago. Still, it is not uniformly defined among institutions, states, countries, or religions. India enacted a law in 1994 to legalize brain-stem death and most of the Indian states have passed this act in their assemblies.

Development of present days critical care units and advancements in medical treatment and technology have improved outcomes and saved the lives of many critically ill patients. The evolution of these life-supporting advances presented unique challenges to physicians faced with the declaration of death following a serious brain insult. Also, with the success of organ transplant programs, the society needed to be made aware of the issues relating to brainstem death, and hence educated and encouraged to proceed towards organ donation.

With the technological advancement, a new concept of death evolved redefining the earlier cardiorespiratory diagnosis to presently a neurocentric diagnosis of death. Brain death is the absence of cortical and brainstem function in an apneic patient receiving circulatory support with a massive structural hemispheric and brainstem injury. For all involved in declaring brain death, there is acceptance, compassion, support, and a deep humanistic appreciation that lives can be saved.

HISTORICAL BACKGROUND

Until the mid-twentieth century, death was defined as failure of circulatory, respiratory, and neurological systems. A person was dead when found to be nonresponsive and with no pulse or spontaneous respiration. However, following developments in the 1950s, all these changed. These developments include the invention of mechanical ventilation with intensive care support and organ transplantation.

To describe the brain death, Mollaret and Goullon in 1959 first used the term '*dépassé*' meaning thereby 'a state beyond coma'. They used this term to refer to neurologic conditions where recovery was impossible.[1] In 1968, an ad hoc committee at Harvard Medical School re-examined the definition of brain death and defined irreversible coma, or brain death, as unresponsiveness and lack of receptivity, the absence of movement

and breathing, the absence of brainstem reflexes, and coma whose cause has been identified.[2] Mohandas and Chou emphasized the role of the brainstem in brain damage in 1971 (Minnesota criteria).[3] A 1976 Conference of Royal Medical Colleges in the United Kingdom described loss of brainstem function as a part of brain death.[4]

The Uniform Determination of Death Act, which became law in 1980, defines brain death as death[5]. It was supported in 1981 by a landmark report issued by the President's Commission for the Study of Ethical Problems in Medicine and Behavioral Research.[6] For diagnosis of brain death, in 1995 American Academy of Neurology (AAN) published the practice parameters. The parameter emphasizes on irreversible coma (with a known cause), absence of brainstem reflexes and irreversible apnea. The diagnosis of brain-death is clinical in nature and supplementary tests to be used in the presence of confounding factors.[7]

In 2010, fifteen years after its first report, the AAN issued an evidence-based guideline update. It concluded that, in adults there are no published reports of recovery of neurologic function after a diagnosis of brain death using the criteria reviewed in the 1995 American Academy of Neurology practice parameter There is insufficient evidence to determine the minimally acceptable observation period reliability of newer ancillary tests. Apneic oxygenation diffusion to determine apnea is safe.[8]

NEED FOR DECLARATION OF BRAIN DEATH

Question of death is important in resuscitation and organ donation. Once a diagnosis of brain death has been made, continuation of critical care is neither in the interest of the patient nor is ethically acceptable. Acceptance of brain death would reduce human sufferings, help in rational use of the constrained ICU facilities, and increase the availability of organs. Organs can be donated only after the confirmation of brain death by a team of competent persons as prescribed by law.[9] Present Indian law permits declaration of brain death only for the organ donation and not for the withdrawl of life support.

CHALLENGES TO DECLARATION OF BRAIN DEATH

Regional medical, legal, cultural, religious, or socioeconomic factors may require brain death testing beyond the suggested minimal clinical standard. Challenges to death determination are complex due to philosophical, religious, and cultural differences in the and definitions of death, difficulties in performing research in this field, deficits in information and evidence on several aspects of the dying process, controversies regarding the validity of death-determination practices, lack of understanding and/or awareness by the public and health professionals and the emotionally charged nature of the subject.[10]

DEFINING BRAIN DEATH

The brain death definition should be clear, reliable and straight forward. It must be independent of the need to organs retrieval for transplantation, but the diagnosis nevertheless is essential for this to proceed. Definition of the brain death includes the irreversible loss of all functions of the brain, including the brainstem. The apnea, coma and absence of brainstem reflexes are the three essential findings in brain death. In

patients who have suffered a massive, irreversible brain injury of known cause, an evaluation for brain death should be considered.

A patient determined to be brain dead is legally and clinically dead. The diagnosis of brain death is primarily clinical. No other tests are required if the full clinical examination, including each of two assessments of brainstem reflexes and apnea tests, are conclusively performed.[11]

BRAINSTEM DEATH

The brain stem is a stalk-like structure acting as a bridge between the cerebral cortex and cerebellum above and the spinal cord below, relaying information and inputs from the periphery to the brain. Its functions are regulating the rate of respiration through the respiratory center, control of eye movements, reflexes and level of consciousness, perception of pain and the regulation of the cardiovascular system. Brain stem death can be defined as a complex state of inactivity, expressed by the loss of reflexes of the pathways that pass through the brain stem resulting in apnea, loss of eye movements and unconsciousness.[12]

Brain stem death is a clinical diagnosis. The accuracy, reliability, reproducibility and ease of clinical tests application make the process of clinical evaluation sufficient for establishing the diagnosis of brain death. Ancillary tests as neurophysiological and imaging studies are not generally must to confirm brain death. A time variable, repeat clinical evaluation is required based on the age of the patient.

BRAIN DEATH DETERMINATION

Following are the three stages for the brain death diagnosis:

1. Establish that the patient has suffered an event of known aetiology resulting in irreversible brain damage with apnea and coma.
2. Reversible causes of coma are excluded as hypothermia, reversible circulatory, metabolic and endocrine disturbances; use or presence of depressant drugs or neuromuscular blocking agents.
3. To confirm the absence of any brainstem reflexes, perform the bedside clinical tests of brainstem function. The patient must be maintained on a ventilator because spontaneous respiration has been inadequate or has ceased.[13]

CLINICAL EXAMINATION

Clinical examination is based on 3 fundamental findings: (1) Coma, (2) absence of brainstem reflexes, and (3) apnea. Coma is assessed by inducing a pain stimulus to all 4 extremities (e.g. nail beds), trunk (e.g. sternum), and head (e.g. supraorbital nerve or temporomandibular joint). Seven brainstem reflexes must be assessed:

i. Pupils should be fixed at "mid-position"; usually approximately 4 mm, and nonreactive to bright light.
ii. Oculocephalic reflexes (doll's eyes) are tested by rapidly turning the head to side.
iii. Vestibulo-ocular reflex (cold caloric responses) should be absent when irrigating the auditory canal with cold water with the head turned at 30°.
iv. Upon stimulation with a swab corneal reflexes should be absent.

v. A gag reflex should be absent on stimulation of the posterior pharynx.
vi. A cough reflex should be absent with endotracheal suctioning.
vii. Facial muscle movement should be absent in response to deep pressure on the temporomandibular condyles and supraorbital ridges.

APNEA TEST

Apnea testing is essential component for brain stem death confirmation. Apnea test is performed only when all prerequisites have been met with and all other brain stem reflexes are absent. Prior to apnea testing, the patient must be preoxygenated for at least 10 minutes with 5 or more cm H_2O of positive end-expiratory pressure (PEEP) for washing out respiratory nitrogen and facilitate oxygen transport. Minute ventilation is adjusted before apnea testing so that the examination begins with $PaCO_2$ in the normal range. To document baseline $PaCO_2$ and pH, an arterial blood gas (ABG) is obtained after preoxygenation and before commencement of apnea testing. Mechanical ventilation is then discontinued. The traditional technique is to disconnect the ventilator circuit, pass oxygen tubing down the endotracheal tube to the carina and instill 5 to 10 L/min oxygen. The patient is observed for any respiratory effort for at least 5 to 10 minutes and until the $PaCO_2$ is expected to rise to >60 mmHg. An ABG is then drawn and ventilation is resumed. Absence of respiratory effort while the arterial carbon dioxide reaching a critical point (≥60 mm Hg); or a 20 mm Hg increase in the pCO_2 over the baseline value, constitutes a positive apnea test that is consistent with brain death. The apnea test must be aborted if the patient becomes hypoxic or hemodynamically unstable.[14] If respiratory movements are observed, the apnea test is negative (i.e. it does not support the clinical diagnosis of brain death) and the test should be repeated.

Observation Period

The length of observation required to determine brain death is variable in adults and children. The recommended observation period in adults is six hours, with longer periods, up to 24 hours, recommended in cases of hypoxic-ischemic encephalopathy. In children, the recommended observation period is age dependent; a 48-hour evaluation interval for infants age seven days to two months; for more than two months to one year the observation period is 24 hours; and 12 hours for those between 1 and 18 years.

Examiner(s)

The examiner making the diagnosis of brain death should be familiar with the clinical criteria and comfortable in performing all aspects of the examination. It is recommended that the brain death examiner be someone other than the treating physician. In case, when organ donation is being considered, the examiner should not be the same physician or surgeon who is part of the transplant team or has responsibilities to the potential recipient of one or more organs.

Ancillary Tests

Ancillary tests are optional and are indicated for the situation when clinical diagnosis cannot be completed or is doubtful. These situations include inability to adequately

examine the cranial nerves, presence of neuromuscular paralysis, heavy sedation, when the apnea test cannot be completed or to shorten the duration of the observation period. Ancillary testing is also required for infants less than one year; two positive tests are required for those less than two months of age. Following are the ancillary tests performed for determination of brain death.

BRAIN BLOOD FLOW

i. Four-vessel conventional cerebral angiography
ii. Computed tomographic angiography
iii. Magnetic resonance angiography
iv. Transcranial Doppler
v. Nuclear perfusion scan (SPECT with Technetium 99m hexamethylpropylene-amine oxime)

Electrical Activity in Brain

i. Electroencephalogram (EEG)
ii. Bispectral Index Scale (BIS)
iii. Evoked potentials (EP)

FOUR-VESSEL CONVENTIONAL CEREBRAL ANGIOGRAPHY

Four-vessel cerebral angiography is the gold standard method of assessing intracranial blood flow. Brain death is confirmed by demonstrating the absence of intracerebral filling at the level of the carotid bifurcation or circle of Willis. The external carotid circulation is patent, and filling of the superior sagittal sinus may be delayed. Posterior circulatory arrest is usually at the level where the vertebral arteries penetrate the dura. The major limitation of catheter angiography is that it is invasive, and the contrast material used for angiography may impair graft function when kidneys are procured and transplanted.

Computed Tomography Angiography

Computed tomography angiography (CTA) was first reported as an ancillary test in the diagnosis of brain death in 1998 as having 100% specificity.[15] It is readily available, relatively inexpensive, minimally invasive, and fast, but need precision performance. Diagnostic criteria include lack of intracranial arterial contrast opacification, defined as vertebrobasilar circulation within the dura and within the internal carotids above the clinoid. The limitation of CTA is, uncertainty regarding the specific radiographic criteria used to identify cessation of brain blood flow required.

Magnetic Resonance Angiography

Determination of brain death by MRA is based on the same criteria as CTA. On MRA, arterial blood flow absence supports the diagnosis of brain death. In addition, magnetic resonance imaging (MRI) also shows variable degrees of cerebral edema and mass effect. However, this may be challenging in an ICU unstable patient with concerns of magnet incompatibility with lines, ventilator tubing and other hardware.

TRANSCRANIAL DOPPLER

Transcranial Doppler ultrasonography (TCD) is safe, noninvasive, bedside, relatively quick to perform and interpret test for brain blood flow. TCD needs visualization of internal carotid and basilar artery in each hemisphere with demonstration of an abnormal flow pattern. Abnormalities consistent with brain death include small systolic peaks in early systole without diastolic flow, or reverberating flow, indicating high vascular resistance associated with increased intracranial pressure. Complete absence of flow is not reliable, as it may result from inadequate transtemporal windows. In some cases, a transorbital approach can be used as an alternative when a temporal window cannot be identified.[16]

NUCLEAR PERFUSION SCAN

Radionuclide imaging is noninvasive and does not require the use of potentially nephrotoxic contrast material. Radioisotopes used are Tc 99m hexamethylpropylene-amine oxime (HMPAO) and Tc 99m ethylene cysteine diethyl ester (ECD), both of which are lipophilic and penetrate effectively into the brain parenchyma. Planar imaging is performed in combination with single photon emission computed tomography (SPECT). Brain death confirmed by absence of uptake of isotope in brain parenchyma and/or vasculature (hollow skull phenomenon). Because of rerouting of blood flow into the external carotid circulation, there is typically accumulation of radiotracer in the nasopharyngeal region, referred to as the "hot nose" sign.[17]

ELECTROENCEPHALOGRAM (EEG)

EEG is the most commonly applied ancillary test for brain-death worldwide. EEG measures the summation of synaptic potentials in the cerebral cortex closest to the brain surface. The electrocerebral inactivity or electrocerebral silence defined as the absence of EEG activity exceeding 2 μV in amplitude, when recording from scalp electrode pairs 10 or more centimeters apart, with interelectrode impedance below 10,000 ohms is the characteristic EEG finding in brain death.[18] The EEG is affected by hypothermia, drug administration and metabolic disturbances reducing its clinical utility. The ICU setting may result in false readings due to electronic background noise creating artifacts.

BISPECTRAL INDEX SCALE (BIS)

Raw EEG data is used to generate a score between 0 and 100 in BIS, where levels below 60 to 70 correlate with lack of awareness. BIS values with a reduction to zero have been associated with brain death. Since the BIS scores are derived from EEG data, they are vulnerable to limitations as those in EEG.

SENSORY EVOKED POTENTIALS

The use of multimodal evoked potentials in the diagnosis of brain-death was described by de Tourtchaninoff et al.[19] SSEPs and brainstem auditory evoked potentials (BAEPs) have limited utility as ancillary tests. Evoked potentials assess relatively discrete pathways in the brain, such that their absence does not prove brain death. The

persistence of evoked potentials is inconsistent with the concept of brain death. The bilateral absence of the parietal sensory cortex responses (N19-P22) in response to median nerve stimulation is supportive of brain death. The absence of brainstem responses to an auditory stimulus (Waves III to V) in the presence of preserved cochlear response (Wave I) is required for a BAEP result to support the diagnosis of brain death.

SUMMARY OF BRAIN DEATH DETERMINATION

Harvard Criteria (1968)

- Unreceptivity and unresponsivity
- No movements or breathing
- No reflexes
- Flat electroencephalogram
- Exclusion of hypothermia (below 90°F or 32.2°C) and central nervous system depressants
- All the above tests shall be repeated at least 24 hours with no change.

Minnesota Criteria (1971)

- No spontaneous movement
- No spontaneous respirations when tested for a period of 4 min at a time
- Absence of brain stem reflexes
- A status in which all the findings above remain unchanged for at least 12 hours
- Electroencephalogram is not mandatory
- Spinal reflexes have no bearing on the diagnosis of brain death
- Brain death can be pronounced only if the pathologic process for the above are deemed irreparable with presently artificial means.

United Kingdom Criteria (1976)

- Establish etiology
- Exclude mimicking conditions
- Absent motor response
- Absent brainstem reflexes
- Apnea with a pCO_2 target of >50 mmHg
- Prolonged observation in anoxic-ischemic injury
- Temperature should be >35°C

US President's Commission Criteria (1981)

- Absent papillary, corneal, oculocephalic, oculovestibular, oropharyngeal reflexes
- Apnea with pCO_2 greater than 60 mmHg
- Absence of posturing or seizures
- Irreversibility demonstrated by establishing cause and excluding reversible conditions (sedation, hypothermia, shock, and neuromuscular blockade)
- Period of observation determined by clinical judgment
- Use of cerebral flow tests when brainstem reflexes are not testable, sufficient cause cannot be established, or to shorten period of observation.

CARE OF BRAIN DEATH PATIENT

Care of brain death patient is important in the context of organ donation. There occurs various physiological changes and complications in brain death patients. These changes may affect the wellbeing of the donor organs. Care of brain death patients amounts to organ harvesting thereby the healthy organs are transplanted in the prospective recipient for the better outcome.

The physiological changes in the brain death patient include cerebral ischemia causing vagal activation with bradycardia and hypotension. This is followed by the pons ischemia, stimulating the Cushing response of sympathetic stimulation with parasympathetic modulation resulting in moderate hypertension and bradycardia. Sympathetic stimulation without parasympathetic modulation causes a "sympathetic storm". Severe hypertension and tachycardia occur, which may in turn be responsible for the myocardial dysfunction encountered in brain death patient. Finally, herniation of the cerebellar tonsils results in autonomic paresis. This is associated with hypotension due to vasodilation from sympathectomy and vasopressin deficiency combined with left ventricular dysfunction as well as hypovolemia from diabetes insipidus.

The management strategies include aggressive resuscitation including advanced cardiac life support, blood transfusion and thyroxine supplementation to maximally support every potential organ donor. In adults, a simplified approach for managing brain dead or dying patients is the "Rule of 100s." Maintain a SBP more than 100 mm Hg using vasoactive drugs, intravenous fluids, and blood products. Maintain PaO_2 greater than 100 mm Hg. Maintain urine output of approximately 100 ml/hr by monitoring for and treating hypervolemia, hypovolemia, and diabetes insipidus. Enteral nutrition should be considered, as it may diminish inflammatory effects of brain death on organ dysfunction.

BRAIN DEATH: THE INDIAN PERSPECTIVE

India follows the UK concept of brainstem death. The Transplantation of Human Organs (THO) Act was passed by Indian parliament in 1994 which legalized the brain-stem death.[20] In 1995, THO rules were laid down which describe brain-death certification procedure. The Government Resolution underlines the responsibilities of hospitals registered under THO Act, 1994 that is, authorized transplant centers. As the large number of brain-death occurs in nontransplant hospitals, it makes for the appropriate authority (Director of Health Services) to register all hospitals in the state that have an operation theatre and ICU as Non-Transplant Organ Retrieval Centers (NTORCs). These hospitals are permitted to certify brain-death as per procedure and then conduct organ retrieval for therapeutic purposes but not permitted to perform actual transplantation. Thus, it is mandatory now for all NTORCs and authorized transplant centers in the state to certify and notify the brain-death cases to Zonal Transplantation Co-ordination Committee (ZTCC). This is an important step to streamline the procedure for cadaveric organ retrieval and transplantation.

ORGAN DONATION PROCEDURE IN INDIA

The medical expert registered with appropriate authority need to have a dialogue with the relatives about carrying of the tests for brain stem death for organ donation. Given the situation and delicate sentiments of family/caregivers, the person responsible

for breaking news to family/caregivers about patient's brainstem death, should be sensitive to the responses and feelings of the family members/caregivers. Form 10 should be filled and signed by the medical experts certifying brain stem death. The primary consultant/treating physician should communicate the confirmation of brainstem death to the transplant coordinator who in turn can communicate with the deceased family members to request for the organ donation.

Once the consent for organ donation is obtained, the cost for maintenance of cadaver or retrieval or transportation or preservation of organs or tissues, their transportation and preservation may be borne by the recipient or institution or government or non-government organization but not by the donor family.

The process of consent for organ and tissue donation involves: (i) The deceased, (ii) next of kin, and (iii) the coroner's consent (medicolegal cases).

i. **The deceased:** The deceased wishes must be ascertained through hospital staff, relatives, or transplant coordinator. In India, even if the deceased wishes are known, the next of kin needs to formally consent and sign the consent form.[20] The NOTTO Organ Donor Register is a computerized database which records the wishes of people who have pledged for organ and tissue donation and decided that, after their death, they wish to leave a legacy of life for others. There are many hospitals and organizations maintaining the names of persons who have pledged organ donation with them; all these are the part of NOTTO website for National Register.
ii. **Next of kin consent:** Hospital staff needs to speak with the relatives about organ donation on behalf of deceased. The surrogate decision-making authorities include spouse, son, or daughter (18 years or over) and parent. In case of dispute or difference of opinion in the family, sufficient time should be given to the family to discuss, settle and give a final decision. Form 8 needs to be filled and signed to record the status-cum-consent by near relative or lawful possessor of brainstem dead person.
iii. **Coroner's consent:** It is necessary to inform police about organ donation consent to the Station House Officer or Superintendent of Police or Deputy Inspector General, if it is a documented medicolegal case.

CONCLUSION

Declaration of death has medical, social, ethical, financial, and legal implications. There is a paucity of evidence-based literature on practices of brain-death determination. Review of literature demonstrates that there is no international consensus even on what constitutes brain death. An individual could be considered legally dead in one country but not in another.

Most agree that the clinical diagnosis of brain stem death is sufficient for certification of death. In spite of the available guidelines, variations and inconsistencies demands the need for an international consensus to define when a person can be declared brain dead. The clinical evaluation criteria must be adhered to and the limitations of confirmatory tests recognized.

In the present time of successful organ transplant programs, acute shortage of organs and availability of large number of brain death patients as potential organ donors; the timely and appropriate diagnosis and declaration of brain dead should be encouraged, facilitated and implemented for the benefit of society at large.

REFERENCES

1. Mollart P, Goulon M. Le coma dépassé. *Rev Neurol* 1959;101:3-15.
2. A definition of irreversible coma. Report of the Ad Hoc Committee of the Harvard Medical School to Examine the Definition of Brain Death. *JAMA*. 1968;205:337–40.
3. Mohandas A, Chou SN. Brain death: A clinical and pathological study. *J Neurosurg* 1971; 35:211–8.
4. Diagnosis of brain death. Statement issued by the honorary secretary of the Conference of Medical Royal Colleges and their Faculties in the United Kingdom on 11 October 1976. *Br Med J* 1976; 2:1187–8.
5. Uniform Determination of Death Act. Available from: http://www.lchc.ucsd.edu/cogn_150/Readings/death_act.pdf.
6. President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, Defining Death: Medical, Legal and Ethical Issues in the Determination of Death. Washington, D.C.: Government Printing Office; 1981. Available from: http://www.euthanasia.procon.org/source files/Pres Comm Defining Death.pdf.
7. American Academy of Neurology Practice parameters for determining brain death in adults (summary statement). The Quality Standards Subcommittee of the American Academy of Neurology. *Neurology* 1995;45:1012–4.
8. Wijdicks EF, Varelas PN, Gronseth GS, et al. Evidence-based guideline update: determining brain death in adults: report of the Quality Standards Subcommittee of the American Academy of Neurology. *Neurology* 2010; 74:1911–8.
9. Ganapathy K. Brain death revisited. *Neurol India* 2018; 66:308–15.
10. D. Sam D. Shemie, Andrew Baker. Uniformity in Brain Death Criteria. *Semin Neurol* 2015; 35:162–68.
11. Goila AK, Pawar M. The diagnosis of brain death. *Indian J Crit Care Med* 2009;13(1):711.
12. J Saran, Jagadish R Padubidri. Brain stem death: An Overview. *Medicolegal Journal* 2019 Mar; 87(1):18–20.
13. Robin S Howard. Coma and brainstem death. *Medicine* 2016; 44(8):495–98.
14. Mack Drake, Andrew Bernard, Eugene Hessel. Brain Death. *Surg Clin N Am* 2017;97:1255–73.
15. Dupas B, Gayet-Delacroix M, et al. Diagnosis of brain death using two-phase spiral CT. *Am J Neuro Radiol* 1998;19(4):641–7.
16. Soldatos T, Karakitsos D, et al. The value of transcranial Doppler sonography with a transorbital approach in the confirmation of cerebral circulatory arrest. *Transplant Proc* 2010; 42(5):1502–6.
17. Mishkin FS, Dyken ML. Increased early radionuclide activity in the nasopharyngeal area in patients with internal carotid artery obstruction: "hot nose". Radiology 1970;96(l): 77–80.
18. American Clinical Neurophysiology Society. Guideline 3: Minimum Technical Standards for EEG Recording in Suspected Cerebral Death. Available at: http://www.acns/org/pdf/guidelines/Guidline-3.pdf.
19. de Tourtchaninoff M, Hantson P, et al. Brain death diagnosis in misleading conditions. *QJM* 1999;92:407–14.
20. Government of India. Transplantation of Human Organs Act, 1994. Central Act 42 of [cited 2019 Dec 26]. Available from: http://www. medindianet/tho/thobill1asp.

Chapter 7

Autopsy: When, Why, How, Where?

Ajay Vinayak Patil

In 1969, after Parliament passed *Registration of Births and Deaths Act*, registration of the events of death and birth became mandatory. Thereafter, in case of death, not only the occurrence of death, but cause also gained its due importance.

But what if the treating doctor is not sure of the cause of death? or even if the cause of death is presumably known by circumstances, other possibilities are needed to be ruled out given legal inquiry into the cause of death? Many a times allegations/grievances warrant postmortem examination or autopsy for deduction/concluding the exact cause of death.

Before understanding the details of the autopsy, lets first discuss how the occurrence of death is recorded by way of certification, i.e. MCCD (medical certificate of cause of death).

Medical certification of cause of death (hereafter referred to as MCCD) in India is commonly called **"Death Certificate"**.

It should be understood with great clarity that declaring death is different than the certification of death. It may happen that in an emergency a doctor is seeing the patient who is already dead, or the patient may be in gasping condition, and succumbs. Here the doctor may not know the cause of death, hence it may not be in capacity to certify MCCD.

But after examination of the vital parameters, etc. of the patient, still can 'declare' the patient as dead. Hence, 'declaration' of death is different than 'certification' of death, and the terms should not be used interchangeably.

IMPORTANCE OF DEATH CERTIFICATION (MCCD)

Legal and Protective Uses

For claiming family allowance, hospital reimbursement, life insurance claims, obtaining a probate or succession certificate, settling inheritance/property claims, releasing gratuity and provident fund claims, and deleting the deceased name for the Ration Card, and Voter's list or employer's register, etc.

Administrative Uses

As indicators of the existence of infection and epidemic diseases and the need for immediate control measures. For public safety, accident prevention, and eradication

programs. In clearing of documents such as disease case registers, social security files, tax registers, etc.

Statistical Uses

In planning and evaluation of development plans. Useful in public health and medical research such as, in the study of mortality and the trends in mortality by age, sex, and cause. The registration records thus are primarily useful for their value as legal documents and secondarily as a source of vital statistics.

Legal Provisions

Medical certification of cause of death under civil registration system has got statutory backing under Sections 10(2) and 10(3) of the Registration of Births and Deaths Act, 1969.

The registrar after making the necessary entries in the **register of birth and death,** forwards the certificates to the Chief Registrar or officer deputed by him, by 10th of every month, after the month when the certificate was issued. Section 17 (1) (b) of the Registration of Births and Deaths Act any person can obtain an extract relating to any death, provided he pays the necessary dues/fees as per the existing government norms. However, the information on the cause of death, will not be disclosed unless it is in the interest of the public.

It is the responsibility of the signing medical practitioner to forward the death certificate to the registering authority, although this is usually sent through a relative of the deceased, who receives a permit from the municipality to dispose of the dead body only after presenting the death certificate for registration—as per the RBD Act. *(Registration of Births and Deaths Act)*.

Under Section 23(3) of the RBD Act, any medical practitioner who neglects or refuses to issue a certificate under Section 10(3) and any person who neglects or refuses to deliver such certificate shall be punishable with fine, which may extend to fifty rupees.

Role of Medical Officer/Medical Practitioner

The medical officer has two tasks at hand.

First: To diagnose the occurrence of death, i.e. permanent disappearance of all evidence of life. Once it is concluded that the person is dead, a "**Death Report"** is forwarded to the Death Registry Authority (along with the MCCD).

Second: To decide the cause of death. It is the morbid condition to which can be traced the sequence of events ultimately resulting in death. Deaths due to natural causes.

Procedure and Practice

The death events are recorded at the place of occurrence, in the office of the Registrar of births and deaths for that area. On the occurrence of death, the informant specified by the RBD Act, 1969 (Head of the house, In-charge of a Medical Establishment, Jailor in-charge of a jail, Incharge of hostel, Dharamsala, boarding-house, lodging-house, tavern, barrack, public resort, etc.), for such an event has to declare the fact of the event along with certain particulars to the registrar of birth and death for that area.

POSTMORTEM EXAMINATION[1]

Medicolegal Postmortem (Examination)

Autopsy is a postmortem examination of the dead body. It is a word that is identical to the word, i.e. necropsy.

There are two types of autopsies that are there, one is medicolegal autopsies, with which we are primarily concerned where stales come into the picture because crime has occurred or a suspected crime has occurred or at least it is certain that the death that has occurred, it cannot be said with certainty that the death is due to natural causes.

Other is the clinical autopsy or pathological autopsy that is done after obtaining the consent of the nearest kin or nearest relative. It can be incomplete autopsy. If relations want that only the heart should be opened and seen 'whether myocardial infarction has taken place, the doctor is authorized to do only that part of the examination of the human body. This clinical autopsy can be partial, but postmortem examination in medicolegal cases cannot be partial autopsies; they have to be complete autopsies.

Postmortem examination is conducted with the following objectives:

1. To find out cause of death
2. To find factual, objective, medical information for law enforcement agencies and court.
3. To allow proper recovery and preservation evidence
4. To document injuries and disease
5. To determine the manner of death
6. To know the time of death
7. To reconstruct crime scene
8. To provide correlation of facts and circumstances related to the death (treatment/surgery, etc.)
9. To help in the identification of victims, etc.

Medicolegal Postmortem Examination/ Medicolegal Autopsy is being requested by Investigative Agencies: Police under Section 174 Cr PC and/or Magistrate under Section 176 CrPC.

For understanding the regulations better, refer below mentioned relevant legal provisions regarding conducting an autopsy.[1]

CENTRAL GOVT ACT: SECTION 174 IN THE CODE OF CRIMINAL PROCEDURE, 1973

Section 174: Police to enquire and report on suicide, etc.

1. When the officer in-charge of a police station or some other police officer specially empowered by the state government in that behalf receives information that a person has committed suicide, or has been killed by another or by an animal or by machinery or by an accident, or has died under circumstances raising a reasonable suspicion that some other person has committed an offence, he shall immediately give intimation thereof to the nearest Executive Magistrate empowered to hold inquests, and, unless otherwise directed by any rule prescribed by the state government, or by any general or special order of the District or Subdivisional

Magistrate, shall proceed to the place where the body of such deceased person is, and there, in the presence of two' or more respectable inhabitants of the neighborhood, shall make an investigation, and draw up a report of the apparent cause of death, describing such wounds, fractures, bruises, and other marks of injury as may be found on the body, and stating in what manner, or by what weapon or instrument (if any); such marks appear to have been inflicted.

2. The report shall be signed by such police officer and other persons, or by so many of them as concur therein, and shall be forthwith forwarded to the District Magistrate or the Subdivisional Magistrate.
3. When:
   i. the case involves suicide by a woman within seven years of her marriage, or
   ii. the case relates to the death of a woman within seven years of her marriage in any circumstances raising a reasonable suspicion that some other person committed an offence concerning such woman, or
   iii. the case relates to the death of a woman within seven years of her marriage and any relative of the woman has made a request in this behalf, or
   iv. there is any doubt regarding the cause of death, or
   v. the police officer for any other reason considers it expedient so to do, he shall. subject to such rules as the state government may prescribe in this behalf, forward the body, with a view to its being examined, to the nearest civil surgeon, or other qualified medical man appointed in this behalf by the state government, if the state of the weather and the distance admit of its being so forwarded without risk of such putrefaction on the road as would render such examination useless.
4. The following Magistrates are empowered to hold inquests, namely any District Magistrate or Subdivisional Magistrate and any other Executive Magistrate specially empowered in this behalf by the state government or the District Magistrate.

CERTAIN DAY-TO-DAY QUESTIONS/SITUATIONS FACED BY MEDICAL PRACTITIONERS

Waiving off Postmortem (Examination)

Medicolegal postmortem (examination) is done on request of Police/Magistrate/Court.

Treating Doctor/Medical Officer has no power to waive off a postmortem examination. He can play the role of an advisor in such cases but the final decision lies with Investigative Agency (Police or Magistrate).

Complete or Incomplete Postmortem (Examination) Procedure

As on today in India, complete postmortem (examination) is carried out in medico-legal cases, i.e.

1. Examination of clothing /items over the body.
2. External examination of the body from head to toe, front, back, and sides.
3. Internal examination with the opening of all the three cavities, i. e. dead, chest, and abdomen.

There is no practice or provision of incomplete or partial or limited postmortem (examination) in medicolegal cases. Partial postmortem examination is practiced in clinical autopsies (non-medicolegal cases).

Court Cases in Short and Description in Nutshell for Understanding Legal Point of View

A. Case in short: First reported as death due to paralysis, after exhumation and autopsy was found out that death was due to shock and hemorrhage due to vaginal injuries:
Initially, the mother had been told that her daughter died of paralysis and she was buried at the bank of Manorama river. Later on she got information from residents of the same village that her daughter had been raped and killed. Mother made a request that the dead body of the child be exhumed and sent for postmortem. On the order of the concerned Subdivisional Magistrate, the dead body of Renu was dug out from the grave and sent for a postmortem examination. In the autopsy surgeon's opinion, death was due to shock and hemorrhage as a result of antemortem vaginal injuries (*Supreme Court of India, Ramesh Harijan vs state of UP on 21 May, 2012, Author: B Chauhan, Bench: B.S. Chauhan, Dipak Misra*).[2]

B. Case in short: First reported in death certificate as cardiac arrest, then after suspicion from close relative medicolegal autopsy revealed as death due to asphyxia—smothering:
The doctor who examined the patient, issued a certificate stating that the patient had died of cardiac arrest. However, as per the postmortem done a few days later, the cause of death was found to be asphyxia as a result of smothering. The appellant was roped in as an accused committing murder and was put to trial. Both the sessions court as well as the High Court have found the appellant guilty of the offences under Section 302 and Section 201 of IPC. (In the *Supreme Court of India, criminal appellate jurisdiction, criminal appeal no. 2202 of 2014, Ananda Poojary appellant(s) vs State of Karnataka [arising out of special leave petition (criminal) no. 7185 of 2013.*)[3]

C. Case in short: First reported as natural death, then turned into medicolegal case after foul play suspected:
It was not then a medicolegal case; the need for postmortem had arisen, because the peon had noticed certain marks on the neck, which had caused some suspicion. After discovering that the mark on the neck was a postmortem injury, all that he had to do was to verify whether the diagnosis made by the G.T. Hospital that death was due to diabetic coma was admissible. (*Supreme Court of India, Anant Chintaman Lagu vs the State of Bombay on 14 December, 1959, equivalent citations: 1960 AIR 500, 1960 SCR (2) 460, Author: Hidayatullah, Bench: Hidayatullah, M.*)[4]

D. Case in short: A postmortem examination alone could rule out the possibility of accidental, suicidal or homicidal cause of the death. (Also in deaths after treatment in hospital, even if the doctor 'thinks' he 'knows' the cause of death.)
In the absence of the postmortem examination concerning the cause of death of Anuradha, it must be held that the death was a natural one. The death certificate issued by the Breach Candy Hospital, Mumbai, was not a conclusive proof of the cause of death but was only a tentative one. It was silent about the antecedent

cause or other significant conditions contributing to the death. The death certificate could not rule out the possibility of accidental, suicidal, or homicidal cause of death. In this connection it is also to be mentioned that the death certificate alone cannot rule out the possibility of accidental, suicidal or homicidal cause of the death.

A postmortem examination alone could rule out the possibility of these three kinds of death... (accidental suicidal or homicidal cause of the death) (*Supreme Court of India, Malay Kumar Ganguly vs Sukumar Mukherjee and others on 7 August, 2009, Author: S Sinha, Bench: S.B. Sinha, Deepak Verma*).[5]

E. Case in short: Who can order/decide for medicolegal autopsy? The requisitions for conducting the postmortem are submitted not only by the police officers but also by the Executive Magistrates in some select cases.

In the high court of judicature at Madras, dated: 16.04.2019, Coram: the Honourable Justice Mr. S. Manikumar and the Honourable Justice Mr. Subramonium Prasad w.p. no. 10694 of 2019).[6]

GUIDELINES FOR ISSUING OF MCCD

Medical practitioner can issue the certificate of cause of death. Issuing MCCD is done immediately after deciding the person is dead, by the same doctor who has declared the person dead, provided that the doctor is **certain about the cause of death** and if it is a **natural death**. There should be no delay, for any reason, in issuing the medical certificate of cause of death, once the doctor is sure of the cause of death.

The doctor should not sign a medical certificate of cause of death in advance (i.e. before the individual has died) or without viewing and examining the dead body personally.

In some establishments the death certificate is to be counter-signed by the Medical Superintendent (legally not required), who should do it only after a personal examination of the body.

The death report (Form 4) and MCCD (Form 8/8A) should reach the registrar within 14 days of the occurrence of death.

No fee is to be charged for issuing the certificate.

He should not withhold issuance of medical certificate of cause of death even if his dues have not been cleared by the relatives.

MCCD should not be issued and the dead body should not be released if:

a. The injured is brought dead.
b. A crime has already been registered by the police.
c. The police have already been informed about the case.
d. The cause of death is not known.
e. The death during treatment of the patient is unexpected, unexplained, and due to unknown reasons.
f. Death following surgeries, procedures, etc.
g. If there is an allegation of negligence about treatment of patient, etc. (Deaths in which even if the doctor knows the medical cause of death or is aware of medical/scientific fact/complication to the best of his knowledge).

In case it is an **unnatural death**, the body should be handed over to the police, who holds an inquest and sends the body for postmortem examination. However, the doctor is responsible to inform the registrar about the occurrence of death. The registrar can note the event of the occurrence of death and mention in the column of cause of death that the inquest report is awaited. This may hold in brought-in-dead cases in the hospital also.

REFERENCES

1. Anil Kohli, Tabin Millo, Mukta Rani, SK Verma, Asit K Sikary, Shalini Girdhar. Uniform Guidelines for Postmortem Work in India: Faculty Development on Standard Operative Procedures (SOP). *Journal of Forensic Medicine and Toxicology* Vol. 30, No. 1 & 2, January-December 2013.
2. B Chauhan, Bench: BS Chauhan, Dipak Misra. Supreme Court of India, Ramesh Harijan vs State of UP on 21 May, 2012.
3. In the Supreme Court of India, Criminal appellate jurisdiction, criminal appeal no. 2202 of 2014, Ananda Poojary appellant(s) vs State of Karnataka [arising out of special leave petition (criminal) no. 7185 of 2013.
4. Hidayatullah, Bench, Hidayatullah, M. The State of Bombay on 14 December, 1959, Equivalent citations: 1960 AIR 500, 1960 SCR (2) 460.
5. S Sinha, Bench: S.B. Sinha, Deepak Verma). Supreme Court of India, Malay Kumar Ganguly vs Sukumar Mukherjee and others on 7 August, 2009.
6. In the high court of judicature at Madras, dated: 16.04.2019, Coram: the Honorable Justice Mr S. Manikumar and the Honourable Justice Mr Subramanium Prasad w.p. no. 10694 of 2019).

Chapter 8

Retinopathy of Prematurity

RK Maheshwari, BD Gupta

Retinopathy of prematurity (ROP) is a disorder of the developing retinal blood vessels in preterm low birth weight infants and is a leading cause of childhood blindness. Previously it was known as retrolental fibroplasia.[1] It is a disease which is forseeable as well as preventable by appropriate measures if taken timely.[2]

The retinal vascularization happens centrifugally from optic disc to ora serrata. Vascularization up to nasal ora serrata is completed by 8 months (36 weeks) and temporal ora by 39–41 weeks to complete a normal vascular retina.[1,3] Thus, in almost all term infants the retina and retinal vasculature are fully developed hence there are almost no chances of ROP. However, in prematures since the development of retina is incomplete, there are chances of ROP.

Incidence

Due to improved survival rate of neonates particularly prematures the incidence of ROP is increasing in our country. This disease is amongst one of the leading causes of preventable blindness in our country.[4] Indian studies have reported ROP in 20 to 52% of screened neonates. More recent studies reporting lower rates of ROP ranging from 20 to 30%,[5] whereas a study from Telangana (India) reports an incidence of 2.3% among NICU admissions.[6] The disease is said to be more common in male infants.[7]

Etiopathology

The exact etiology of ROP is yet not known. Development of blood vessels in the eyes is normally completed a few weeks before term birth. An infant who is born early is exposed to many different things, viz. medicine, oxygen, bright lights, or temperature changes which might affect development of eye vessels hence lesser the gestational age at birth more the risk. Many risk factors have been shown to be associated with development of ROP as listed below.

The retina in premature infants is incompletely vascularized or completely avascular at birth depending upon the degree of prematurity (more premature the child, lesser vascularized retina the child will have at birth). There occurs an initial vasoconstriction and then rapid growth of blood vessels in the retina leading to leaking of blood vessels and the lesion heals by scarring. These scars can later shrink and pull on the retina, leading to retinal detachment, blindness, etc. The disease advances from stage 1 to 5. Up to stage 3 it is treatable by laser or cryotherapy. Vision can be restored even at stage 4 but in stage 5 the vision loss is permanent.

The premature infant is not born with ROP, the retina though immature is normal for this age. It is the postnatal developments in the retinal vessels which can lead to ROP. The ROP usually evolves slowly over 2–5 weeks after birth. In this period, the clinician should carry out retinal examinations and if necessary intervene timely to improve visual outcome and prevent irreversible blindness as a result of retinal detachment.[3] However, it may not be possible to exactly predict which premature baby will develop ROP and to what extent and why.[8]

It must also be noted that nearly one-third to half of neonates undergoing screening may show some degree of ROP but in a large no. of cases it regresses on its own but in a few unfortunate cases it progresses and if unchecked may lead to retinal detachment vis-à-vis blindness.[5]

Risk Factors

There are many factors which are closely associated with the incidence of ROP. They are:

1. Prematurity and low birth weight
2. Poor postnatal weight gain
3. Oxygen therapy (hypoxia/hyperoxia) or prolonged oxygen exposure (>30 days)
4. Mechanical ventilation
5. Intraventricular hemorrhage
6. Exposure to light
7. Blood transfusion, anemia
8. Unstable clinical course
9. Late onset sepsis (including Candida sepsis)
10. Pneumothorax
11. Hypotension
12. Acidosis, RDS, apneic episodes
13. Multiple births (twins/triplets)

On the contrary, breastfeeding and kangaroo mother care is said to reduce incidence of ROP.[9]

SCREENING PROTOCOL: WHO SHOULD BE SCREENED?

ROP might not be visible until some weeks after birth[10] hence premature babies at risk for ROP must be screened postnatally. The guidelines about which infants should be subjected for screening differ from country to country. The guidelines of Rashtriya Bal Swasthya Karyakram, Ministry of Health and Family Welfare, Govt of India (RBSK-GOI)[5], Clinical Practice Guidelines of NNF India (NNF-CPG)[3] and the guidelines of American Academy of Pediatrics (AAP)[11] in this context have been compared below in Table 8.1.

Table 8.1: Various guidelines for selection of prematures for ROP screening

Criteria	*RBSK-GOI*	*NNF-CPG*	*AAP*
Birth weight	≤2000 g	≤1750 g	≤1500 g
Gestational age	≤34 weeks	≤34 weeks	≤30 weeks
Infants ranging between cut off birth weight and 2000 g with unstable clinical course and/or associated with risk factors	Yes, to be screened	Yes, to be screened	Yes, to be screened

The acute-phase ROP screening should be based on the infant's postmenstrual age because the onset of serious ROP correlates better with postmenstrual age (gestational age at birth plus chronologic age) than with postnatal age as depicted in Table 8.2. This signifies that more preterm the child is at birth, longer would be the time to develop serious ROP.[5,9,11]

Table 8.2: Timing of first eye examination based on gestational age at birth[11]

Gestational age at birth (weeks)	*Age at initial examination (weeks)*	
	Postmenstrual	*Chronologic*
22*	31	9
23*	31	8
24	31	7
25	31	6
26	31	5
27	31	4
28	32	4
29	33	4
30	34	4
Older gestational age, high-risk factors**	—	4

* This guideline should be considered tentative rather than evidence-based for infants with a gestational age of 22 to 23 weeks because of the small number of survivors in these postmenstrual age categories.
** Consider timing on the basis of the severity of co-morbidities

Timing of Screening

The guidelines/recommendations of NNF-CPG and RBSK-GOI (3, 5) in this context are as follows:

- The first screen should be performed not later than 4 weeks of age or 30 days of life in infants ≥28 weeks of gestational age.
- They may also be screened by the third week of life to enable diagnosis of aggressive posterior ROP (AP-ROP).
- Infants <28 weeks or <1200 gm birth weight should be screened early at 2–3 weeks of age, to enable early identification of AP-ROP.

Frequency of Screening/Follow-up Examinations

The follow-up frequency of screening depends on the status of patient and should be done as depicted in Table 8.3.

Table 8.3: Showing follow-up frequency for screening

Zone of retinal finding	*Stage*	*Follow-up interval*
No signs of ROP		2–3 weeks intervals until the retina is fully vascularized
Zone 1	Immature vasculature	1–2 weeks
	Stage 1 or 2	1 week or less
	Regressing ROP	1–2 weeks
Zone 2	Immature vasculature	2–3 weeks
	Stage 1	2 weeks
	Stage 2	1–2 weeks
	Stage 3	1 week or less
	Regressing ROP	1–2 weeks
Zone 3	Stage 1 or 2	2–3 weeks
	Regressing ROP	2–3 weeks

Termination of Screening

As per the RBSK guidelines[5] the screening examinations should continue at least every two weeks until:

- Vascularization of the retina reaches normal completion, or
- ROP regresses, or
- ROP requiring treatment develops.

Procedure for Retinal Examination

The retinal examination must be done by an ophthalmologist (preferably pediatric ophthalmologist). The parents/relatives must be informed about the screening, the risk of ROP, need of follow-up, etc. in detail and their consent must be taken and recorded/documented. Ideally the baby should be examined in a NICU under a radiant warmer.

Pupillary dilatation is usually done by a combination of cyclopentolate 0.5% and phenylephrine (2.5%) drops. Atropine should not be used for dilatation. The retina is examined under topical anesthesia using an indirect ophthalmoscope. As far as possible, sedation should not be given. Digital photographic retinal images by RETCAM that are captured and sent for remote interpretation is a developing alternative approach to ophthalmoscopic ROP screening. All findings must be recorded in the chart/card using standard notations. The date of subsequent follow-up should be clearly stated.

Transition of Care

Many-a-times patient is to be discharged before he/she has completely recovered (e.g. before retina develops up to anterior zone III or even after treatment there is incomplete regression or incomplete retinal healing or maturation). In such circumstances the transferring/discharging pediatrician must mention all details on the discharge card including present status and ensure timely follow-up either by seeking appointment with the ophthalmologist or entrusting the job to the relatives to get the child examined by the ophthalmologist. Parents/relatives must be told about the risk of ROP and possible prognosis as well as importance of timely follow-up. All these must be documented.

Long-term Follow-up

Infants with ROP are prone to develop visual disorders, e.g. squint, amblyopia, myopia, retinal detachment and cataract. Prematurity also predisposes to refractory errors, strabismus and lenticular opacities. Hence, such babies should be followed-up intensively up to first six months and then less intensively up to adulthood to identify/treat long-term complications timely.

Medicolegal Implications

In recent years, many doctors have been implicated by the courts in India. Some doctors take these guidelines lightly and do not advise screening at all, there are some who do advice but do not document and third category is of doctors who do all the things half heartedly. In terms of law there is hardly any difference between the first and second category but the third category persons are also not spared by law.

It is difficult for parents to accept that their child has gone blind particularly when they are told that this could have been prevented. Hence, once it happens, the chances of their suing doctors are much more in comparison to other situations.

1. **What doctors must do:**
   - If a preterm neonate has risk factors which could lead to ROP (e.g. if he/she requires oxygen therapy or mechanical ventilation or if he/she is hemodynamically unstable during the course of treatment), the treating registered medical practitioner (RMP) must communicate with the parents and tell them in details about the risk factors, possible outcome, etc. Better communication with parents and documentation always minimizes legal complications.
   - If the doctor is not a neonatologist, he must seek his opinion and the advice given must be shared with the relatives.
   - The treating doctor/neonatologist must advise ROP screening by a trained ophthalmologist (preferably pediatric ophthalmologist) as per the guidelines and must advise proper follow-up as per the guidelines.
   - Documentation of all activities is a must.
   - If patient is not brought for follow-up timely as per the advice given to him, it must also be recorded.
   - Discharge ticket must be prepared very carefully. It must mention details of screening, follow-up advice, etc. Everything must be clearly written in a way that parents cannot claim in the court that they failed to take the desired meaning.
   - Parents have a right to take their child to another centre who in their opinion can deliver better. If they exercise this option, the doctor must never refuse them to give details of treatment, etc. given in their hospital.
   - Netizens must be dealt with in a patient way and doctors must develop skill to reply them.
2. **Rights of patient:**
   - The parents/relatives have a right to know all details of treatment, risk factors, possible outcome and alternative treatment options, etc.
   - They have a right to obtain all copies of treatment schedules, expert opinion, investigations.
3. **Role of hospital:**
   - Hospital must employ proper qualified personnel.
   - It is the duty of hospital that all the pieces of equipment are of good quality and are in perfect condition. The patient should not suffer because of equipment failure or because of untrained or unqualified personnel.
   - Proper recordkeeping
   - Hospital administration must ensure that their doctors do spare time to discuss the condition of patients with their relatives just on the lines of parents–teachers meeting done in schools. It is important as the hospitals have also been made to pay compensation on account of vicarious liability they have.

Relevant Judgments of Courts

1. **V. Krishnakumar vs. State of Tamil Nadu and others. Decided by Hon'ble Supreme Court on 1 July, 2015[8]:** The salient features of this case are as follows:

- On 30.8.1996, the appellant V. Krishankumar's wife Laxmi was admitted in Government Hospital for Women and Children, Egmore, Chennai (Govt sector Hospital). She delivered a low birth weight female child (1250 gm) prematurely (29th week of gestation). Child remained in hospital for about 25 days, remained in ICU also, received 90–100% oxygen and also had exchange transfusion. In the discharge summary the respondent doctors wrote: "Mother confident; Informed about alarm signs; (1) to continue breast feeding, (2) to attend postnatal OP on Tuesday." The child was seen at 9 weeks of age by respondent doctors but still screening for ROP was neither advised nor done.
- At 4.5 months of age, another pediatrician at Mumbai diagnosed ROP but by then she had already reached into 5th stage of ROP. Parents took her to many ophthalmic centers in India as well as in US but could not revert blindness.
- The Hon'ble Supreme Court (SC) upheld the judgment of National commission in this regard. The plea of respondent that "informed alarm signs" was turned down by court. The Court observed that these remarks are only a hastily written general warning and nothing more.
- Total compensation of 1.86 crores (including interest from date of filing of complaint) equivalent of 0.6 million dollars was awarded.
- About 5% of the compensation was ordered to be paid by the doctors and the rest by the Hospital and Government of Tamil Nadu.

2. **Maharaja Agrasen Hospital vs Master Rishabh Sharma. Decided on 16 December, 2019 by Supreme Court. (Appeal No. 6619 Of 2016)[12]:** The salient features of this case are as follows:
   - Mrs Pooja Sharma delivered a child at Sharma medical centre (by LSCS for placenta previa) at 32 weeks of gestation and birth weight of baby was 1.49 kg. Same day the child was referred to Maharaja Agrasen Hospital. At admission the condition of child was poor and was diagnosed as preterm AGA with HMD. Baby was put on ventilator support also.
   - Patient was discharged after about 27 days with "Diagnosis: PT (32) with HMD with neonatal hyperbilirubinemia with B/L pneumothorax fungal septicemia. Condition at time of discharge: Satisfactory." There is no advice to the complainants to have the ROP test carried out on the baby in the discharge slip. Follow-up done at about 4 weeks and then at 3 months of age again no ROP screening was advised.
   - At about 8 months of age her ROP was diagnosed by an ophthalmologist but by that time the child was already in stage 5 of ROP.
   - The parents demanded medical records from Agrasen Hospital but it was denied in spite of legal notice. Parents approached Delhi Medical Council and ultimately after >2 years the copy of medical records were given.
   - Scrutiny of medical record showed that ROP screening was done by hospital's ophthalmologist at about 24 days of age. Parents denied that any such examination was done and they maintained that they were never informed about this. They alleged that the records have been fabricated and interpolated as an afterthought to escape liability.

- The National Commission sought an expert opinion from AIIMS. The medical board opined that ROP screening in prematures should be done at 3–4 weeks of age and during follow-up. Board admitted that an ophthalmologist had done ROP screening at 24 days of age. Board also observed that the child was not brought to hospital for follow-up after two weeks of discharge as advised. However, the National Commission was not convinced that ROP screening was done at 24 days of age as there was no mention of this in nurses daily record, etc. The Commission awarded a compensation of 64 lakhs.
- Both the parties went in appeal in Supreme Court (SC). The Hon'ble SC observed that withholding the medical records for a period of over 2 years, constitutes grave professional misconduct apart from being a gross deficiency in service on the part of the Appellant no.1: Hospital and its management. Hon'ble SC observed discrepancy in the notes of ophthalmologist and rejected the claim of hospital that the child did not come for follow-up as advised by them. The court observed that the ROP screening was neither advised nor carried out at all by the hospital, or the senior ophthalmologist, throughout the period of hospitalization of the baby, or even after discharge. SC found the treating doctors guilty of negligence and opined that the medical records were interpolated to cover up. The Hon'ble SC thus allowed a compensation of 76 lakhs.

3. **Kumari Shivani Singh vs. Dr Ashwini Gokhale. Decided by National Consumer Disputes Redressal on 30 November, 2006. Equivalent citations: I (2007) CPJ 326 NC[13]:** The salient features of this case are as follows:
   - The complainant delivered her child on 17.5.1994. The child had diarrhea after few days of delivery. The gynecologist tried to consult pediatrician on phone but failed. So, she prescribed syrup Wallamycin. She also advised parents to bring syrup Gramoneg but it was to be given only after pediatrician's advice. The complainants alleged that syrup Gramoneg was administered to the baby by the gynecologist herself and the child later on developed ROP due to this drug.
   - The court, however, did not find any force in the appeal and no compensation was awarded.
4. **Akash Mayur Shridharani vs. Dr Sharmila Mallya and others. State Consumer Disputes Redressal Commission[2,14]:** The salient features of this case are as follows:
   - The baby was born prematurely in a private hospital with weight 1280 gm at age of 28 to 30 weeks but since the child was premature she was shifted to another hospital where she was kept under ventilator for 2½ days and subsequently in incubator for 22 days. During this period, she was under treatment and observation of Dr Mallya and Dr P Surekha. She was discharged after about 24 days.
   - After about 2.5 months she was again admitted in same hospital for 2–3 days. She again went for follow-up after about 10 days and her treatment slip mentions about eye exam and shown it to be WNL (i.e. within normal limit).
   - At about 6–6.5 months of age ROP was diagnosed by an ophthalmologist (patient's relative). By that time the child was in stage V of ROP.

- Complainants alleged that ROP screening was not advised to them. While the doctors denied allegations and said they did inform parents to get ENT and ophthalmological opinion to identify any feasible defect at the time of first discharge as well as on follow-up. About WNL which is the observation recorded in the examination/treatment papers, doctor's stance was that the said finding was in respect of external eye examination and not in respect of vision which was not checked?
- Court did not agree with the pleas of doctors and ordered a compensation of 5 lakhs.

5. **DMC vs. Sanjiv Bhasin State Consumer Disputes Redressal Commission. Decided on 16 April, 2012[15]:** The salient features of this case are as follows:
   - The child was born at 31st week of gestation via cesarean section. At the time of birth the child's weight was about 1.34 kg. She was kept in nursery and was given oxygen and discharged after 38 days. She was examined on 8th day by an ophthalmologist but no ROP was found. Further ROP screening at 4–6 weeks as per protocol was not done. There was no mention of ROP on discharge ticket and thus no instructions were given to parents about follow-up for screening of ROP.
   - By the time ROP was detected, it had already reached 5th stage.
   - Treating doctors claimed that ROP screening was done at 8th day, she was advised for further screening but patient defaulted. But court did not agree with their defense.
   - The Court observed that there was gross deficiency in service. Court felt that the doctor did not inform the complainants about the seriousness of the disease and the requirement of regular screening.
   - The appeal of treating doctors was dismissed with costs and complainants were awarded compensation.

CONCLUSION

ROP is a disease of developing retinal vasculature. The incidences of ROP as well as litigations due to it are on increasing trend. It is high time that those who deal with newborns must be very particular about this preventable blindness disease and newborns must be screened as per the protocol. Doctors must develop a habit of properly documenting and communicating with the parents. One must remember if we give time to parents, we will need not to give time to our advocates.

REFERENCES

1. Garg B. Retinopathy of prematurity. https://www.slideshare.net/barun_garg/retinopathy-of-prematurity-71794374 Accessed on 1.6.2020.
2. Nagpal Neeraj, Nagpal Nimisha. The Retinopathy of Prematurity: Legal Conundrum. *Journal of Indian Medicolegal and Ethics Association*. 2017, 5, 6-13.
3. Retinopathy of Prematurity. NNF Clinical Practice Guidelines. https://www.ontop-in.org/ontop-pen/Week-12-13/ROP%20NNF%20Guidelines%20.pdf Accessed on 1.6.2020.
4. Anand Vinekar, Chaitra Jayadev, Shwetha Mangalesh, Mathew Kurian, Mangat Dogra, Noel Bauer, et al. Initiating Retinopathy of Prematurity Screening before Discharge from the Neonatal Care Unit: Effect on Enrolment in Rural India. *Indian Pediatr* 2016;53:107–111.

5. Guidelines for Universal Eye Screening in Newborns including Retinopathy of Prematurity. Published by Rasthriya Bal Swasthya Karyakram, Ministry of Health and Family Welfare, Govt of India, June 2017.
6. Le C, Basani LB, Zurakowski D, Ayyala RS, Agraharam SG. Retinopathy of prematurity: Incidence, prevalence, risk factors, and outcomes at a tertiary care center in Telangana. *J Clin Ophthalmol Res* 2016; 4:119–22.
7. Lokanandha Reddy. Retinopathy of Prematurity. at https://www.google.com/search?rlz = 1C1CHBD_enIN870IN871&sxsrf=ALeKk02DUYdoN4jpqYcu4QxItdBDh2j7tQ: 1591597700225 & source=univ & tbm=isch & q=RETINOPATHY + OF + PREMATURITY + - + Dr. + LOKANADHA + REDDY & sa = X & ved = 2ahUKEwi2-q-8y_HpAhWM63 Accessed on 1.6.2020.
8. V Krishnakumar vs State of Tamil Nadu and Others; https://indiankanoon.org/doc/86607695/ Accessed on 2.6.2020.
9. Rajan Shukla , GVS Murthy, Clare Gilbert , Bala Vidyadhar , Sridivya Mukpalkar. Operational guidelines for ROP in India: A Summary. *Indian J Ophthalmology* Feb 2020. Accessed at http://www.ijo.in/ on 2.6.2020.
10. Boyd K. What is Retinopathy of Prematurity (ROP)? https://www.aao.org/eye-health/diseases/what-is-retinopathy-prematurity#:~:text = Retinopathy%20 of %20 prematurity% 20 (ROP)% 20 is, brain%20so%20you%20can%20see. Accessed on 2.6.2020.
11. Walter M. Fierson. Screening Examination of Premature Infants for Retinopathy of Prematurity. American Academy of *Pediatrics*. Pediatrics 2018; 142: 1–9.
12. Maharaja Agrasen Hospital. vs Master Rishabh Sharma. https://indiankanoon.org/doc/35792279/ Accessed on 2.6.2020.
13. Kumari Shivani Singh vs Dr Ashwini Gokhale. https://indiankanoon.org/doc/1884713/ Accessed on 2.6.2020.
14. Akash Mayur Shridharani vs Dr Sharmila Mallya and Others. https://www.casemine.com/judgement/in/5909ee2a4a932663936bff9b on Accessed on 3.6.2020.
15. DMC vs Sanjiv Bhasin. https://indiankanoon.org/doc/40136277/Accessed on 3.6.2020.

Section

2

Procedural Complications

9. Complications after Injections and AEFI
10. Checklists: How to Design?
11. Sudden Decision of LSCS or any Unexpected Surgery
12. Postoperative Complications

Section Editors: Rishi Bhatia, Suresh Vashistha

Chapter
9

Complications after Injections and AEFI

BB Sahni

A common cause of claims in medical profession is injection errors. While generally low in value, they frequently cause anxiety to patients and clinicians, and are easily avoided. Many times these errors are lifethreatening or a cause of permanent disability

Preventable injection errors leading to complications could be wrong injection, wrong dose, wrong route, expired date and lack of consent.

- Injection injuries are rare types of injuries that involve a small puncture wound and often damage to surrounding areas. Generally, this wound is underestimated both by a patient and by a doctor. Some people are shocked and dismayed to find that an inappropriately injected substance or an injection in the wrong location of the body or incomplete a septic precautions can result in significant tissue damage, Abscess, an amputation, or nerve damage.[1]
- If a doctor is grossly negligent and the patient dies as a result, the doctor can be charged with manslaughter.
- The numbers of doctors charged with and convicted of manslaughter have increased appreciably in the past decade.[2]

Nurses who depart from the accepted standards of nursing care and cause harm by injecting in the wrong site, injecting the wrong substance, or otherwise making injection errors may be held liable for medical malpractice.[1]

If patients can establish liability, they may be able to recover economic and noneconomic damages. Economic damages may include medical expenses, rehabilitation, therapy, replacement services (such as household services), out-of-pocket costs, and the costs of any necessary surgeries and disability compensation. Noneconomic damages are intangible losses. Most of the time, they are not documented and are based on what a judge believes would naturally flow from the kinds of injuries sustained. They can include pain and suffering, mental anguish, and loss of enjoyment. Often, the individual characteristics of the plaintiff will determine the amount of pain and suffering or loss of enjoyment experienced as a result of the injection injury. For example, if a patient's right hand develops nerve damage as a result of an injection injury, and he is a right-handed tennis player, there may be more pain and suffering associated with this situation than if he were left-handed.[1]

VICARIOUS LIABILITY

A hospital or a doctor can be held vicariously liable for mistakes by its staff in case injection errors especially if the staff is under qualified.

1. The National Consumer Disputes Redressal Commission (NCDRC) held the hospital and the treating doctors guilty of medical negligence and said that they were liable for the death of the three-year-old girl Arshia who was suffering from blood cancer.
   The commission noted that the girl was administered an injection wrongly which deteriorated her situation eventually leading to her death in July, 2004.
   "We are of the considered view that the doctor is vicariously liable for the acts of his team which assists him in every sphere in rendering treatment to the patient," said the commission's bench comprising President RK Agrawal and member M Shreesha. Its order came in the case of Arshiya, daughter of a Ludhiana-based couple Prashant and Anjali Sareen, who was being treated for blood cancer in Mohan Dai Oswal Cancer Treatment and Research Foundation Hospital there.[3]
2. Spring Meadows Hospital vs KS Ahluwalia, 1998: In this case due to wrongly injecting antimalarial drug lariago intravenously a child went into vegetative state for whole life by an underqualified nurse, a fine of Rs. 25 lakhs was imposed on hospital.
   The Commission found that there was clear dereliction of duty on the part of the nurse and that the hospital was negligent in having employed an unqualified person as nurse and entrusting the child to her care.[4]

WRONG DOSE

Case 1

A 4-year-old boy who had a brain tumour removed had been given 650 mg of methotrexate "into the brain," developed convulsions, and subsequently died. The dose of methotrexate was 20 times too great. The junior doctor who had given the injection had taken the dosage from the case notes, "not knowing that it related only to intravenous drips." (The circulating blood volume is about 20 times the volume of cerebrospinal fluid.) The doctor was charged with manslaughter but was acquitted.[2]

Case 2

A general practitioner performed circumcisions on four boys in his surgery and administered diamorphine to them as a sedative. One 9-year-old boy remained unconscious and when he was eventually taken to hospital he was found to have suffered irreversible brain damage from which he died. The doctor at first claimed he had given the boy dihydrocodeine. He pleaded guilty to manslaughter, having used "excessive amounts of these drugs, and it was accepted that they were wholly inappropriate as sedatives." The doctor was sentenced to 12 months in prison, suspended for 12 months.[2]

NECESSARY STEPS TO DEAL COMPLICATION

Maharashtra: Court provides relief in a case where doctor took necessary steps.[6]

The case relates to the patient, Vidhyavasini K Rajbhar, who approached Dr Sanjay P Patil on March 14, 2009, with complaints of chest pain. The patient was given an injection diclofenac sodium in his right buttock as a treatment. The doctor clearly stated that he had followed the standard practice of giving the injection and once the

complication took place accidentally, took all the steps necessary to treat the complication. His advocate also submitted that as per the Bolam test the doctor has exercised the ordinary skill and followed the accepted standard practice. The learned advocate also submitted that the expert opinion given by Dr C.S. Kambli states that there are inherent risk factors of giving an injection in patients with poor muscle mass.

JUDGEMENT

One can get such injury even at the best hands, due to various factors discussed by the expert opinion. As the doctor recognised the injury immediately and took steps to treat the same, he has followed accepted practice and used ordinary skill needed. We disagree with the learned Additional District Forum that there was medical negligence based on the affidavits of witnesses and the concession certificate later obtained by the complainant. Hence, we hold that there is no deficiency in service given by the doctor to the complainant and no medical negligence on the part of appellant doctor.

CONSENT

Informed consent is necessary before potentially harmful injection if it is not for life-saving procedure especially if for investigative purpose. PGIMER, Chandigarh, was asked to pay Rs 40000 for not taking consent from a lady who had to undergo amputation of her hand after a contrast injection for MRI. Disposing of a complaint filed by Prabhjot Kaur, 32, a resident of Kathe village in Hoshiarpur district, the District Consumer Disputes Redressal Forum directed PGIMER and Dr Khandelwal of department of radio-diagnosis and imaging to pay Rs 40,000 as compensation for deficient services and causing mental agony and harassment to Kaur.[7]

AEFI

The new guidelines define adverse events following immunization (AEFI) as any untoward medical occurrence which follows immunization and which does not necessarily have a causal relationship with the usage of vaccines. These events may include one or more unfavorable or unintended sign, symptoms or laboratory findings which raise concern among immunization program managers, policy makers, family of beneficiary and the community.[8]

New classification: In 2012, revised classification relevant to cause-specific categorization of AEFIs has been introduced.[9]

Cause-specific Type of AEFI

Definition

1. *Vaccine product-related reaction*: An AEFI that is caused or precipitated by a vaccine due to one or more of the inherent properties of the vaccine product.
2. *Vaccine quality defect-related reaction*: An AEFI that is caused or precipitated by a vaccine due to one or more quality defects of the vaccine product, including its administration device as provided by the manufacturer.
3. *Immunization error-related reaction*: An AEFI that is caused by inappropriate vaccine handling, prescribing or administration and thus by its nature is preventable (formerly 'program error').

4. *Immunization anxiety-related reaction*: An AEFI arising from anxiety about the immunization.
5. *Coincidental event*: An AEFI that is caused by something other than the vaccine product, immunization error or immunization anxiety.

Types of AEFIs by Severity and Frequency

1. Common minor AEFIs
2. Severe AEFIs
3. Serious AEFIs

Common Minor AEFIs

A vaccine induces immunity by causing the recipients immune system to react to the vaccine. Therefore, local reaction, fever and systemic symptoms can result as a part of the immune response. In addition, some of the vaccine components (e.g. adjuvant, stabilizers or preservatives) can lead to reactions.

Severe and Serious AEFIs

An AEFI will be considered serious if it results in death, requires hospitalization, results in persistent or significant disability/incapacity or a cluster (two or more cases) of AEFIs occur in a geographical area.

AEFIs that are not minor but do not result in death, hospitalization or disability are categorized as severe.

DUTIES OF DOCTOR

Common Vaccine-induced AEFIs

Parents should be given advice about AEFIs that they can expect and how such events should be managed. The leaflets on vaccinations provided by the Department of Health give information about AEFIs and include advice on their management.

Fevers over 37.5°C are common in children and are usually mild. Advice on the use and appropriate dose of paracetamol liquid to prevent or treat a fever should be given at the time of immunisation. Local reactions are usually self-limiting and do not require treatment. If they appear to cause discomfort, then paracetamol or ibuprofen can be given.

Aspirin, or medicines that contain aspirin should never be given to children under 16-year-old because of the risk of developing Reye's syndrome.

Rare Vaccine-induced AEFIs

Some other AEFIs occur rarely and include those that are neurological or immune-mediated. Examples include seizures, hypotonic-hyporesponsive episodes (HHE), idiopathic thrombocytopenic purpura (ITP), acute arthropathy, allergic reactions and anaphylaxis.

Anaphylaxis

Anaphylactic reactions to vaccines are extremely rare but have the potential to be fatal.

Onset of anaphylaxis is rapid, typically within minutes, and its clinical course is unpredictable with variable severity and clinical features. Due to the unpredictable nature of anaphylactic reactions it is not possible to define a particular time period over which all individuals should be observed following immunisation to ensure they do not develop anaphylaxis.

Medicines to manage anaphylaxis, e.g. injection adrenaline, hydrocortisone, inj avil, IV fluids, oxygen, etc. should always be available at immunisation centres.[10,11]

1. Keep record, lot, batch no. and manufacturer name.
2. Maintain cold chain
3. Preserve the vial and other materials if sudden anaphylaxis occurs for further investigation.
4. Report to govt. authority

AEFI Reporting

The reporting of serious/severe AEFI is done using case reporting format (CRF) (formerly first information report), which is prepared by the Medical Officer of the PHC or the reporter and then sent to the District Immunization Officer within 24 hours of getting the information of the case. In the next 24 hours, the DIO verifies the case details and sends it simultaneously to the state and national level. The CRF gives only the most basic details of the affected person, vaccines and session details and status at the time of filling the format.

The other channel of reporting serious and minor AEFI from the level of occurrence of the AEFI up to the national level is through monthly progress reports. This is done using existing monthly immunization reporting formats such as the ones for National Rural Health Mission (NRHM), Health Management Information System (HMIS), etc. It is necessary for the peripheral health staff to submit a NIL monthly report in case no AEFI is detected from their area during the month. Minor AEFIs that are brought to the notice of the health staff as a concern should be reported and documented in a line list.

The DIO along with the members of the District AEFI Committee visits the immunization site, vaccine storage points, residence and locality of the patient and the treatment center to collect information regarding the pre-vaccination health status, treatment taken, hospitalization or postmortem reports, details of vaccination and cold chain.

Vaccine Risk Communication and Handling of Media

Effective communication around vaccine safety including management of public reactions requires serious investment of resources and efforts towards strategic communication for immunization.

An AEFI response protocol has standardized procedures for communication to help handle a crisis promptly and in the correct manner. It identifies the spokesperson who will respond in crisis situations at all the levels.

The protocol recommends that in case of media interest in an AEFI crisis, a press release should be issued as early as possible (preferably within first 6 hours). The quick response by medical team can prevent a potential harm to immunization programme in that area and also a violent response by crowd.[8]

CONCLUSION

Even though an injection is given with best of intention for treatment or investigative purpose, a complication whether due to error on the part of treating team or anaphylaxis can lead to serious social or medicolegal problem. The treating team must be fully equipped to deal with anaphylaxis or minor complications and be prepared to arrange for higher consultations. Errors have to be avoided by total team to avoid vicarious liability. An AEFI if not handled properly can lead to a major setback to immunization program in a widespread manner.

REFERENCES

1. www.defransisco.com injection injury.
2. R E Ferner. Medication errors that have led to manslaughter BMJ. 2000 Nov 11; 321(7270): 1212–16. doi: 10.1136/bmj.321.7270.1212. PMCID: PMC1118964.
3. Doctor liable for acts of his team assisting in rendering treatment, says NCDRC. Economic Times, May 30, 2019, 08.12 PM IST.
4. Supreme Court of India. M/S. Spring Meadows Hospital & Anr vs Harjol Ahluwalia Through, K.S. ... on 25 March, 1998. Author: G Pattanaik. Bench: S. Saghir Ahmad, G.B. Pattanaik.
5. Dr Dawn McGuire, Medical Claims Adviser at Medical Protection, Injection errors. Post date: 12/09/2018 Membership information 0800 561 90006.
6. Accidental Injection Injury not negligence: State Forum gives relief to Doctor: medical dialogues published on 12 Jun 2018 12:30 PM: St.
7. Home/Chandigarh/PGIMER asked to pay Rs 40,000 compensation for negligenc Hindustan times Jun 16, 2015 09:22 IST.
8. Adverse Events Following Immunization -Surveillance and Response Operational Guidelines, MOHFW, 2015. http://itsu.org.in/repository-resources/AEFI-Surveillance-and-Response-Operational-Guidelines-2015.pd.
9. Causality assessment of an adverse event following immunization (AEFI). User manual for the revised WHO AEFI causality assessment classification (Second Edition).
10. Vaccine safety and adverse events following immunisation: the green book, Chapter 8 Published 20 March 2013. From: Public Health England.
11. Bohlke K, David RL, Marcy SH. Risk of anaphylaxis after vaccination of children and adolescents. Pediatrics 2003; 112: 815–20.

Chapter
10

Checklists: How to Design?

Jyotika Kalsy, Riya Kaur Kalra

A checklist is a type of job aid used to reduce failure by compensating for potential limits of human memory and attention. It helps to ensure consistency and completeness in carrying out a task.[1] Checklists have been used in health care practice to ensure that clinical practice guidelines are followed. An example is the WHO Surgical Safety Checklist developed for the World Health Organization and found to have a large effect on improving patient safety.[2] According to a meta-analysis, after introduction of the checklist, mortality dropped by 23% and all complications by 40%.[3]

It has been said that medicine which used to be inefficient, simple, and safe, is now effective, highly complex, and dangerous. Adverse events are documented to affect more than one in 25 hospital patients. Failure to check equipment and lack of vigilance are examples of factors associated with adverse events. Realising how prone we as humans are for short-term memory loss, it is striking how many potentially dangerous medical procedures are based on perfect memory. In this context, it is rather strange that checklists are not used more often in medicine.[4]

Checklists have been important tools in ensuring a consistent standard of care in the medical field. Examples include the use of standardized order set checklists and daily check sheets to increase the use of best practices. In one such instance, the implementation of daily checklists and reminders in clinical care pathways for inpatients admitted for acute myocardial infarction or stroke led to significant improvements in compliance with various key best practices such as administration of aspirin in the emergency department (21.4%; 95% CI; 7.3–32.7%), receipt of β-blockers within 24 hours of admission (48.1%; 95% CI; 31.4–64.8%), dysphagia screening within 24 hours of admission (40.7%; 95% CI; 21.0–60.2%) and administration of aspirin or clopidogrel to ischaemic stroke patients within 24 hours of admission (55.4%; 95% CI; 32.9–77.9%), as compared with the period prior to study.[5]

In a study conducted by Redfern E,[6] it was found that the implementation of their emergency department (ED) safety checklist was associated with improvements in key ED clinical performance indicators. There was improved management of time—critical conditions which included a mean increase of over 5% in CT scanning within an hour for patients with a suspected stroke. Additionally, there was a mean increase of 25% in hourly observations and Early Warning Score calculation with no clinical incidents relating to failure or delay in recognising a deteriorating patient. This led them to conclude that checklists, when introduced appropriately, can improve the

standardisation and reliability in delivery of care, resulting in improved patient outcomes.

In another study, Hearns S et al[7] concluded that in terms of time and financial cost, the checklist is arguably one of the most effective methods of reducing medical error and improving performance under pressure. Checklists help to ensure all steps in a task are completed and they reduce stress prior to undertaking high-risk procedures. They improve teamwork effectiveness and reduce cognitive overload when patent deterioration or equipment failure occurs.

Similar studies have been conducted to emphasize the need of checklists in the ED and they have led to a common conclusion that checklists are the need of the hour in the current situation of overcrowded EDs, exit blocks and ambulance queues.

HOW TO DESIGN?

The development of technical documents, such as checklists, requires a systematic and comprehensive approach, particularly when they are to be implemented in high intensity fields such as medicine. Table 10.1 gives a fair idea of the process of designing a checklist.

Table 10.1: Considerations for formatting a medical checklist

Criteria	*Consideration*
Context	Location of the checklist should be determined prior to development. If it is to be stored in a medical record upon completion, the checklist it will need to be processed through the appropriate hospital regulatory bodies
Content	When possible, synthesis of published peer-reviewed guidelines and evidence-based best practices should be considered to form the body of the checklist
	Literature employed for generation of criteria points should be from a broad range of peer-reviewed, reliable sources and include perspectives of all types/disciplines that represent the continuum of intended users. This is particularly important if the medical checklist is to be used by all personnel within a multidisciplinary team of health care providers
	Checklists should also reflect the local hospital and institution policies and procedures
Structure	Checkpoints should be presented in a logical and functional order that reflect the sequence or flow of real-time clinician activities and regular patient care routines.
	If the checklist is to be part of standard patient care, it might be important to include a checkpoint at the end where two users can sign off that it was completed, e.g. space for nurses to confirm that the checklist was completed by the physician.
Images	Clear, equally spaced, bold fonts are suggested for letter differentiation and reading comprehension
	If colours are to be used—ensure that they are consistent with those commonly used in the intended environment, e.g. if red is commonly associated with emergency situations, it should not be used to highlight text unless it is urgent information
	Checklists should include appropriate institutional logos or letterheads if necessary (e.g. if it is to be included in the medical record, it will have to match the format of other forms/orders)
	Checklist should not be so onerous or time consuming as to notably interfere with administration of patient care
	Overall checklist should encompass checkpoints of major importance, while still providing clinicians with the freedom to use their own judgment
	Members of each discipline within a unit should pilot the checklist, particularly if the checklist is to be used by all personnel within a multidisciplinary team of health care providers
Usability	Validation of the checklist should occur, where possible, within the appropriate simulated clinical environment

Examples of Existing Checklists

Examples of published checklists currently employed regularly in the medical field include:

- The checklist for diagnosing brain death[8]
- The anaesthesia gas machine checklist[9]
- The checklist for the withdrawal of life support and end-of-life care[10]
- The FAST HUG checklist of clinical best practices[11]

LIMITATIONS TO THE USE OF CHECKLISTS

Regardless of the systematic approach used to design and develop the perfect checklist, there are subsequent measures that, if not considered, could jeopardize the implementation of the checklist into practice. These can be summarized as follows:[5]

- Users must be properly trained on the use of the checklist in order to achieve optimal results.
- Target users must also have a full understanding of purpose of the checklist, whether it be evaluative or mnemonic, to avoid misinterpretation of checkpoints and erroneous answers.
- The checklist must be extensively piloted, ideally in simulated clinical environments and amongst the population of users in order to evaluate efficacy, practicality and overall need for the checklist.
- Checklist designers or authors might also consider developing an educational plan that introduces the main concepts of the checklist to the candidate users, in combination with a promotional plan to increase awareness of the checklist.
- Usefulness of the checklist requires support of all staff, dedicated champions and endorsement by multidisciplinary leaders in clinical care. Inclusion of the multidisciplinary team during the development of checklists not only improves endorsement, but also contributes to long-term sustainability following implementation and further emphasizes a team approach to completion and 'cross-checking' of the checklist items.

REFERENCES

1. Checklist. Available from: https://en.wikipedia.org/wiki/Checklist#cite_note-Checklists-3.
2. Haynes A; Gawande A. "A surgical safety checklist to reduce morbidity and mortality in a global population". *New England Journal of Medicine* 2009; 360 (5): 491–99.
3. Bergs, J; Hellings, J; Cleemput, I; Zurel, Ö; De Troyer, V; Van Hiel, M. "Systematic review and meta-analysis of the effect of the World Health Organization surgical safety checklist on postoperative complications". *The British Journal of Surgery* 2014; 101(3):150–8.
4. Thomassen, Ø., Espeland, A., Søfteland, E. Implementation of checklists in health care; learning from high-reliability organisations. *Scand J Trauma Resusc Emerg Med* 2011:19, 53 doi:10.1186/1757-7241-19-53. Available from: https://sjtrem.biomedcentral.com/articles/10.1186/1757-7241-19-53.
5. Brigette Hales, Marius Terblanche, Robert Fowler, William Sibbald, Development of medical checklists for improved quality of patient care. *International Journal for Quality in Health Care* 2008;20(1):22–30.
6. Redfern E, Hoskins R, Gray J, Lugg J, Hastie A, Clark c et al. Emergency department checklist: an innovation to improve safety in emergency care. BMJ open quality September 2018;

7:e000325. doi: 10.1136/bmjoq-2018-000325. Available from: https://bmjopenquality.bmj.com/content/7/3/e000325.
7. Hearns S. Checklists in emergency medicine. *Emergency Medicine Journal* 2018;35:530–531. Available from: https://emj.bmj.com/content/35/9/530.
8. Young GB, Frewen T, Barr HW, Hinton GG, Blume WT, Kronick JB, et al. Checklist for diagnosis of brain death, *Can J Neurol Sci* 1991; 18:104.
9. Runciman WB, Webb RK, Klepper ID, Lee R, Williamson JA, Barker L. The Australian incident monitoring study. Crisis management—validation of an algorithm by analysis of 2000 incident reports. *Anaesth Intensive Care* 1993; 21:579–92.
10. Hall RI, Rocker GM, Murray D. Simple changes can improve conduct of end-of-life care in the intensive care unit. *Can J Anaesth* 2004;51:631–6.
11. Vincent JL. Give your patient a fast hug [at least] once a day. *Crit Care Med* 2005;33:1225–9.

Chapter
11

Sudden Decision of LSCS or any Unexpected Surgery

Gouri Gore

Obstetrics is the leading specialty in malpractice suits globally. The obstetrician is responsible for two individuals at a time. Many of the complications occurring during labor are impossible to predict in the antenatal period. Moreover, labor abnormalities are difficult to prove using an investigation to common person. The incidence of LSCS has risen all over due to various reasons. It is the commonest surgery performed. The indications for LSCS are widening. Historical outlook of performing cesarean section in situations where vaginal delivery was impossible has been replaced by a trend to offer LSCS when vaginal delivery is anticipated to have severe maternal or fetal complications. There is an increasing tendency, with advances in NICU care, to perform cesarean for fetal indications for a better fetal prognosis even in premature fetuses. As doctors, we have to acknowledge the fact that there is a common assumption that on many occasions emergency cesareans are being performed without a reasonable indication. It is very difficult to provide a convincing evidence to non-medico-patient and relative—when a patient is in labor without any antenatal risks the doctors keep telling the patient that everything is under control and suddenly the doctor decides to perform emergency LSCS. It is very likely that a complaint will be lodged in such cases particularly when there is severe morbidity or mortality.

Every obstetrician should follow a SOP to minimise the damage in such situations.

DOCUMENTATION

Backbone of a medicolegal case is documents. If the doctor can provide reasonable evidence to suggest that the management was carried out according to prevailing guidelines the judgements generally is in favor of the doctor. Documentation of high-risk factors during antenatal period like pre-ecalmpsia/diabetes should be highlighted in OPD papers of the patient. Clinical findings of pelvic assessment like small pelvis/cephalopelvic disproportion should be mentioned meticulously, in utmost details since this generally is not documented by any investigations. In last few days of pregnancy if the patient has been suggested possibility of difficult vaginal delivery or has been offered LSCS for any relative indication it must be written on the OPD paper. Many a times the patients will reach the hospitals only during labor after this visit.

Sample Clinic Form

Sample linical notes (OPD Paper)

Date: .....

Name: .....

Age: .....

Blood group: .....

LMP: ..... EDD:.....

High risk factors:

GA : Wt : BP :

Complaints: .....

.....

.....

P/A P/S & P/V

Advice:

Medicine	Dosage	Frequency	Duration

Clinical findings explained to the patient. They have been explained about potential complications in vaginal delivery in view of ..... Possibility of LSCS discussed with the patient along with potential complications and risks involved in the procedure. The patient is willing/not willing for instrumental delivery.

Follow-up after .....

Kindly visit ..... Hospital in case of medical emergency

Emergency contact: .....

There are many instances when a patient has filed a case when mother or the baby had to be transferred to other institute after some complication alleging that the said hospital did not have certain facilities about which the patient was not informed. For small hospitals and nursing homes it is very important to display the available facilities or provide information about facilities hospital does not have like ICU or blood bank. At the time of registration it can be documented that patient has been informed about available facilities and hospital arrangments of transferring patient if needed.

I/we have decided to register at ..... hospital. I/we have been given estimate of charges for ..... Hospital. I/we agree to deposit the required amount as per class at the time of registration and admission. We agree to pay the surgeon charges to Dr ..... as per the estimate.

Patient signature Relative signature

Name Name

Date :

Sample registration consent form

Registration at ..... Hospital

I/we have been informed about the following facilities available at ..... Hospital.

	Hospital
Location	XYZ
Obstetrician Team	☑
Neonatologist Team	☑
Labour Room and Operation theatre with emergency care	☑
Basic Newborn care	☑
NST machine and fetal monitor with digital display	☑
Blood Bank	×
Adult ICU	×
Neonatal ICU	×
Cashless Facility	×

Labor process is variable for every patient. Labor monitoring documentation is vital for any obstetric case. Partogram is the best tool for that. The paramedics also can be taught to use a partogram. Federation of Obstetrics and Gynecological Societies of India (FOGSI) has included use of partogram into the guideline for clinical standards to ensure safe delivery.[1]

Documentation of prolonged or obstructed labour, fetal distress either by partogram or clinical notes at different time intervals is a good evidence to justify the indication of LSCS.

Consent

There is a possibility of emergency cesarean section for every patient undergoing labor. The patients must be made aware about it even when uneventful vaginal delivery is anticipated. The principal of informed consent suggests that the patient has to be in sound state of mind without any stress when she signs the consent form. The decision to perform cesarean can be sudden but the paperwork should be initiated earlier. Potential possibility of LSCS must be mentioned in the consent for induction of labor/trial of scar/trial of vaginal delivery.

A fresh consent should be obtained again when LSCS is decided. It should include: indication in clear words, potential requirement of blood transfusions, ICU admission or maternal complications.

Possibility of requirement of NICU care in case of fetal indication should be mentioned. Delay in consent or refusal of consent has to be documented with date and time.

As per the law only patients consent is adequate to perform any surgery including LSCS.

In case patient or relatives agree to give consent later, mention current clinical situation before obtaining the consent for emergency LSCS.

Decision and Surgery Time

This is very important in cases of fetal distress. If LSCS is delayed due to nonavailability of OT/doctors/staff/no deposit, etc. it is perceived as deficiency in the service.

Operation Notes

Standard format for operation notes has to be followed. It should include smallest surgical details and should be in legible handwriting or electronic format. The following points will improve the quality of evidence:

- Condition of mother at induction from incision to delivery time
- Difficulty in approaching the uterus (in case of previous surgery)
- Fetal position: Abnormally lie/impacted head or any other body part easy or difficult delivery/use of vacuum forceps: Any maneuvers used to deliver the baby
- Condition of the baby at birth: Resuscitation methods used.
- Any maternal complication like PPH/extension of incision/bladder or bowel injury and corrective measures.
- Blood loss—transfusion
- Surgery time

Obstetrician's notes, anesthetist notes and neonatologist notes should have continuity of information. Any discrepancy in them will go against the entire team.

POST LSCS COMPLICATIONS

Every complication is not a negligence. However, if the complication is not diagnosed in time or is not managed appropriately it will amount to deficiency in service.

Delayed Complaints due to Fetal Complications

These types of litigations are on the rise. In cases of prolonged labor or difficult delivery/instrumentation—parents of a child with delayed milestones or learning disablities can file a complaint after several years and the delay can be condoned if a cause of action is prima facie seen at the time of delivery. The obstetric records should be preserved for 21 years, but it may be in the doctors interest to preserve record of difficult cases for several years.

Transfer/DAMA

In some cases the patient or the baby has to be shifted to other hospital. A detail transfer note mentioning the need for transfer is important. Every hospital must have a transfer protocol along with the list of higher centres where the patient will be transferred if required.

If the patient takes discharge against medical advise it does not absolve the doctor from all litigations. The patient may file a complaint and the case will be decided based on the treatment offered till the time patient was in the hospital.

As obstetrics practice gets more complicated situations of emergency LSCS and its outbursts will be on the rise. An obstetrician should prepare in each clinical situation to fight the case in the court of law.

Cases

Case 1:[2] Patient underwent LSCS in one hospital and was taken to higher institute due to postoperative pain. A surgical mop was removed at the second hospital. There after the patient developed enterocutaneous fistula and was treated at a third hospital. In the meanwhile the patient also suffered from ophthalmic problems. The comission awarded compensation only for the complication arising due to LSCS at first hospital.[2]

Case 2:[3] Patient underwent LSCS and was discharged. She was readmitted due to abdominal pain and then referred to other hospital where she was told about VVF due to bladder injury during LSCS. It was contended by the doctor in the court that it was a difficult LSCS due to previous 2 LSCS and transverse lie. Court accepted the argument about "bladder injury complication can occur in this case and it is not a negligence."However, the doctor was held liable due to improper management of complication and not revealing the complication to the patient.[3]

Case 3:[4] LSCS was advised due to intrahepatic cholestasis of pregnancy. The patient had postpartum hemorrhage in the immediate postoperative period and was re-explored. Obstetric hysterectomy was done.[4] The comission upheld doctors defense on the following points:

a. LSCS was performed for a justified indication
b. PPH is a known complication during LSCS
c. Detailed surgery notes listed all conservative managements those were tried for PPH control and they failed hence obstetric hysterectomy was done as a life-saving procedure.

So, the complication was handled as per standard guidelines.

Case 4:[5] Emergency LSCS was done for footling breech. There was a fracture femur while the leg impacted in the vagina. Allegations were made that a normal delivery was "Assured" by the doctor but LSCS was performed. This argument was rejected by the court and it was accepted that the doctor acted as per the standard of care. However, the complaint was partially allowed as there was a delay in diagnosing the birth injury and providing treatment.[5]

Case 5:[6] Second gravida known case of bronchial asthma and hypothyroidism was in labor and was offered epidural analgesia. Emergency LSCS had to be performed for fetal distress after epidural. The patient had cardiorespiratory complications and became vegetative even after prolonged treatment.[6] The doctor was held liable due to:

a. Consent was not obtained before giving epidural.
b. Epidural was given inspite of patient requesting LSCS.
c. The doctor did not take into consideration her pre-existing illness before offering her any treatment.

Case 6:[7] Pregnant patient was given blood transfusion due to Evan's syndrome (pancytopenia due to autoimmune disease) following which she underwent LSCS. Thereafter she presented with acute liver failure and required transplant, was diagnosed hepatitis B positive. The patient alleged that infection was due to improper

testing at the time of blood transfusion. The judgement was in favor of the doctors as the documentation of blood bank screening and treatment protocol was produced and was found to be as per the protocol.[7]

REFERENCES

1. FOGSI clinical standard 2016.
2. RP/660/2016 Manju vs Dr. Santosh Bishnoi NCDRC January 2017.
3. 173/2015 Subhash Chandra Singh vs Sarathi Hospital: DCDRC, Kota, Rajasthan (Jan 2020).
4. CC/2240/2016 Resham Bhargava vs Superspecialty Hospital.
5. CC/15/391 Raghav Mulajkar vs Manjusha Sherekar, DCDRC (Aurangabad) (Nov 2019).
6. Manisha Dehran vs JP Hospital, SCDRC, Chandigarh, October 2019.
7. FA/172/2013 : Parvathi Shirisha N vs Yashoda Hpspital, November 2019.

Chapter
12

Postoperative Complications

Rishi Bhatia

Postoperative complications are problems which arise as a result of surgery and are not intended. Surgeons are aware of the risk of complications and take steps before, during and after surgery to reduce the risk. However, some complications are common and occur frequently despite of precautions.

The subject of postoperative complications is so broad that one can hope to deal with it only in a very general way in a single article as the material is so vast that a book only can cover all. It is however, of the very first importance to the physician, surgeon and patient. The unpleasant sequelae arise more frequently in the practice of some surgeons than others. There are many factors that play part in reducing the number of complications. Failure to observe certain fundamental principles of surgery lead to complications sometimes, although there may be other reasons also post-operative complications may be directly related to the disease for which the surgery was done or to the surgery itself.

Postoperative complications may either be general or specific to the type of surgery undertaken and should be managed with the patient's history in mind. The highest incidence of postoperative complications is between one and three days after the operation. However, specific complications occur period wise as early postoperative, throughout the postoperative period, several days after operation and in the late postoperative period.

Some postoperative complications are peculiar to a specific surgery while some may occur after any kind of surgery. The common general postoperative complications include fever, infection, lung collapse, pneumonia, embolism and deep vein thrombosis.

Postoperative complications may be grouped as:

a. Immediate complications (that occur up to three days after surgery) e.g. hemorrhage, lung atelectasis, shock (due to blood loss, acute myocardial infarction, pulmonary embolism, septicemia) cardiac problems (like acute myocardial infarction), pulmonary problems, septicemia, renal failure, electrolyte and fluid imbalance.

b. Early complications (that occur in few weeks after surgery), e.g. pain, bruising, confusion, nausea and vomiting, fever, secondary hemorrhage, wound dehiscence, deep vein thrombosis, acute retention urine, infections like pneumonia, UTI, pressure sores, bowel problems like obstruction, paralytic ileus.

c. Late complications (that occur up to years after surgery), e.g. bowel obstruction due to adhesion, incisional hernia, persistent sinus, keloid formations, relapse of original problem.

GENERAL COMPLICATIONS

Pain

Surgery is obviously painful but modern expertise with painkillers and pain blocking techniques ensure control of pain so pain which is not well controlled is seen as a complication rather than as an expected side effect.

Painkillers include oral drugs, injectibles and local anesthetics, which are infused around the nerves in the spine, or into the wound to add numbness temporarily.

Confusion

Confusion is quite common after surgery particularly in elderly patients. It can be caused by the anesthetic or by other medicines including pain killers. Confusion can occur for several other reasons, including pain, dehydration, disturbed sleep, infection, constipation and electrolyte and metabolic imbalance.

Nausea and Vomiting

These are common reaction to anesthesia. Usually medicines are given along with anesthetics to control it. These are more common with bowel surgery.

Temperature/Fever

It may be caused by tissue necrosis, hematoma, infection in surgical wound, abscess, infection in lungs (e.g. atelectasis, pneumonia), cystitis, phlebitis, deep vein thrombosis, after blood transfusion and as a result of medication.

Septicemia

It is an uncommon complication of surgery, but is serious one which can lead to other problems.

Septicemia is more likely after a surgery which carries a higher infection risk, particularly abdominal surgery involving cutting the bowel, surgery after trauma where wound is contaminated, and severe burns and more in cases where immune system is depressed as in old age, diabetes and persons on steroids.

Other Bodily Injury

There is a small risk of injury whilst under general anesthetic. There can be injury to pharynx, larynx and teeth crowns, neck pain and bodyache is common after prolonged surgery.

Bruising

Bruising is leakage of blood from cut or damaged vessels into the subcutaneous tissue. Bruising is particularly common in patients taking anticoagulants, elderly vitamin K deficiency, nutritional deficiency, clotting disorders, liver diseases.

Hemorrhage (Bleeding)

Bleeding is inevitable in surgery. Bleeding is more common if patient has any bleeding diathesis or using anticoagulants. If it is oozing it settles quickly by pressure. Heavy bleeding is from large vessel which should be sealed off or ligated.

Primary hemorrhage (bleeding during surgery) or reactionary hemorrhage (following postoperative increase in blood pressure) or secondary hemorrhage (due to infection) is managed according to cause by replacing blood loss, re-exploring the wound and using higher antibiotics. If clotting time is abnormal we give fresh frozen plasma, platelet concentrate or protamine. Most of the bleeding can be controlled by firm pressure. Vessels which continue to bleed should be either ligated or cauterised. Only tip of vessel should be ligated or coagulated leaving minimum of foreign material in the wound which is detrimental to hemorrhage.

Continuous bleeding from operation wound: Arvind Kumar Himmatlal Shah represented by L. Rs vs Bombay Hospital Trust, 1992 (2) CPR 154 (Maharashtra): Where the patient died owing to continuous bleeding from the operational wounds. The hospital was held liable for deficiency in service in postoperative care to the patient.

Hematoma

Development of hematoma is very common after any surgery. Hematoma may be under the skin, close to the wound or inside the body where it cannot be seen. Failure to diagnose and treat hematoma may constitute negligence. Ice cold fomentation, pressure or exploration of hematoma are the earliest steps to be taken.

Death due to profuse bleeding after cesarean operation: Devendra Kantilal Nayak vs Dr Kalyaniben Dhruv Shah 1996 (3) CPR 56; I (1997) CPJ 103; 1998 CCJ 544 (Guj.): The patient had undergone cesarean operation and delivered a baby. The patient was bleeding profusely and remained unconscious even after transfusing 8–10 bottles of blood. The patient was shifted to another hospital where she collapsed.

The postmortem report reveals that the deceased had 1.8 litres of hematoma in peritoneum, that some branches of uterine artery showed antemortem cut which were not ligated, and that uterus was repaired deficiently. The findings of postmortem report was corroborated by the evidence of the operating anesthetist who states that the surgeon could not identify and confirm the cause of profuse bleeding, that blood report for clotting mechanism was found normal, and that blood pressure was not recordable even after giving 8 bottles of blood within a span of six hours after the operation.

The State Commission held the surgeon negligent in conducting the cesarean operation.

Surgical Infection

Infection is a natural hazard of all surgical interventions.

Superficial wound infection occurring within the first week causes soreness and localized pain, redness and, sometimes, a slight sticky discharge. It usually responds to antibiotics and local treatment.

Deeper infections are more common after bowel surgery. They can occur anytime from immediately after surgery to up to three weeks later. They can cause high temperature, sometimes with confusion and other constitutional symptoms.

Abcess is more common after abdominal surgery, it can cause swinging fever, confusion and nausea. Abscesses need to be drained.

Wound sinus is a late infection from a deep but undetected abscess that finds a way of discharging through the skin. Patient may have fever but symptoms may not be marked. There may be a sticky discharge often through the surgical scar.

Surgical infection can be reduced by prophylactic antibiotics, higher antibiotics in later stage and proper wound toilet.

Failure to recognize infection may constitute negligence.

Infection during postoperative period: Dr Kanta Prasad vs Nagina Prasad, 2000 (3) CPJ 282: Where infection developed after operation of a person who sustained a fracture of bone in left thigh in a bus accident, it was held, on the basis of medical test reports, that the complainant failed to prove that the treatment was wrong and that there was deficiency in service.

Wound Healing Problems

When operative wound fails to heal by primary union patient's stay in hospital can be prolonged. More serious failure may result in wound dehiscence.

i. **Impaired wound healing may be because of:**
   - Removal of skin and subcutaneous tissue from the two sides of surgical incision.
   - Poor blood supply because of associated diabetes, obesity and smoking.
   - Over-tight stiches can slow healing.
   - Long-term steroids and immunosuppressants particularly oral, make healing slower.
   - Some hormonal problems like diabetes and hypothyroidism tend to cause slower and less strong wound healing.
   - Coughing and strain may cause poor wound healing.
   - Vitamin C deficiency (scurvy) and malnutrition slows wound healing.
   - Radiotherapy damages small blood vessel in skin and cancer can also affect wound healing.

ii. **Wound dehiscence:** It is very upsetting and can be shocking particularly if suddenly wound burst. Dehiscence is uncommon, affecting about one out of hundred large abdominal wounds with mortality of 30%. It usually occurs between 7 and 10 days postoperatively due to failure of wound closure technique. Wound needs to be restitched usually under anesthesia after infection control.

After hysterectomy wound dehiscence and death: Md. Aslam vs Ideal Nursing Home, 1994 (I) CPR 619 (ORI): The patient was admitted in nursing home with profuse bleeding. She was operated for hysterectomy for removal of uterus and ovaries. The wound disruption was noted after eight days of operation. The second operation was taken up for closing abdomen under general anesthesia, but the patient expired.

It was held by the State Commission, Orissa, that the doctor was not negligent in performing the operation and during postoperative care, and that the patient herself was liable for wound disruption by disregarding the advice of the doctor in taking rich food and in allowing large number of visitors which could have caused infection resulting in cough and sneezing.

iii. **Incisional hernia:** Incisional hernia develops as a late complication in about one in ten abdominal surgeries. It is not usually painful and shall not usually strangulate, however, it usually tend to get steadily larger and needs to be repaired. Wound dehiscence, poor wound healing, obesity and poor muscle tone are also more likely to result in incisional hernia.

Sufferings due to improper postoperative care after cesarean operation: Neeru Sharma v Dr Paul B. Singh, 1994 (3) CPR 538 (Ker): The complainant had two children. She conceived for the third time. She got herself admitted to St. Mary's Hospital where the doctor performed cesarean operation. The doctor was not a gynecologist but a general surgeon. The complainant was discharged from the hospital against her wish with pus formation around the operation scar. The doctor on the allegation that owing to removal of stiches without proper healing of internal part of incision and due to deficiency of service during postoperative period, the complainant developed "Incision Hernia" which was cured by another doctor by surgery.

The State Commission, Kerala, dismissed the complaint because no expert evidence was adduced to prove that incisional hernia occurred as a result of any deficiency in the operation or due to any deficiency in service during postoperative period.

The inmate tendency of wounds to heal if placed at rest and protected from external influence along with proper antibiotic coverage would enhance the recovery. For incisional hernia and would dehiscence surgical repair is required.

Precautions

- Irregular crushed edges should be converted to clean regular ones.
- Sterile environment and aseptic precautions in surgery to be taken
- Clean skin incision made at right angle to the surface
- Division of muscles and fascia by sharp dissection
- Avoid powerful and prolonged retraction
- Avoid too tight stitches

Nerve damage: Nerve damage or weakness is due to cutting or excess pressure or traction on the nerve during surgery. The proper course of action is to explore the nerve as soon as possible and to undertake the repair.

Pressure Ulcers

Pressure ulcers are usually more common where bones are closer to skin and in patients with long periods of lying in bed or sitting in a chair without changing position. Pressure sores affect from one to five in every hundred patients admitted in hospital. These are more common in seriously ill, patients with spinal cord injury, or with poor diet. These are common in smokers, diabetics, patients of heart failure and those with neurological diseases. These are treated with good nursing care, pressure relieving devices, analgesics, antibiotics and sometimes plastic surgery may be required.

Sudden Collapse

In postoperative period patient may collapse suddenly. If a patient has a sudden deterioration in the vital parameter it must be promptly managed and informed to

relatives. If the patient needs intensive care or transfer to a higher center, it should be done urgently. After death postmortem should always be advised.

Pulmonary Complications

Lung Atelectasis

This is common and involves a blockage of bronchus leading to collapse of a part of a lung. It is particularly common after abdominal and chest surgery. Collapsed part of the lung can easily be infected by bacteria due to stasis. Atelectasis is more common in obese, smokers and when patient is not able to cough because of pain. Treatment is usually with antibiotics, oxygen and physiotherapy.

Pneumonia

Pneumonia is fairly common though much less common than atelectasis. Usual symptoms are fever dyspnea and may be chest pain.

Deep Vein Thrombosis and Pulmonary Embolism

There is a risk of DVT and PE always after surgery until the patient is mobilized. Pulmonary embolism is very serious and can be fatal. The risk is greatest in surgeries affecting the pelvis. The risk of clotting is increased by being immobile, being obese, hormone therapy, by certain medicines including hormone replacement therapy combined with oral contraceptives, by pregnancy and in smokers. It can be prevented by early mobilization, limbs movement and physiotherapy.

Aspiration Pneumonitis

Aspiration pneumonitis is a rare complication of surgery. It is inflammation of lungs when acidic stomach contents are inhaled, usually due to regurgitation while under anesthesia. It is more common in emergency surgery when a period of fasting is not proper. It can be avoided by crash induction technique of anesthesia and use of injection metoclopramide.

Acute Respiratory Distress Syndrome

ARDS is a serious condition with rapid shallow breathing and severe hypoxaemia which requires intensive care. It is usually seen within 24 to 48 hours after surgery, and after multiple trauma. It causes severe breathlessness and confusion due to low oxygen levels.

Precautions

- Early ambulation
- Cessation of smoking for 2 to 3 weeks before surgery
- Posture, most of the time should be sitting or inclined
- Deep breathing
- Chest physiotherapy
- Steam inhalation

Cardiovascular Complications

Heart problems associated with surgery most often occur within 48 hours following surgery though may occur in first six days. These include heart attack, abnormal heart

rhythms, angina and heart failure. Surgery can trigger a heart problems in an otherwise compensated heart disease. Thrombophlebitis appears in later days of surgery. Deep vein thrombosis may lead to fatal embolism.

John Andrade vs P. D. Hinduja National Hospital and Medical Research Center, 1998 (I) CPR 579 (Bom): It is the duty of the surgeon conducting quadruple vessel coronary artery bypass surgery to diagnose postoperative sternal infection early and give prompt pus culture.

Lekh Raj vs Bharat Nursing Home, 1998 (2) CPR 450 (Chandigarh): The vascular injury for multiple fractures of arm and leg must be referred to the vascular surgeon within 6 to 8 hours, in default vascular injury may lead to formation of gangrene and delay in referring the patient may amount to negligence.

Precautions

- Frequent change of posture
- Active movement of limbs
- Early mobilization
- Avoid prolonged pressure upon calves
- Avoid excessive concentration of blood
- Judicious use of anticoagulants
- Preoperative cardiac assessment

SPECIFIC COMPLICATIONS

Renal System

Urinary Retention

This is very common after surgery, particularly of abdomen or pelvis. It is often caused by pain and settles with pain relief, it is sometimes necessary to catheterize the patient.

Cystitis

UTI or cystitis is common after surgery especially in women particularly after catheterization.

Symptoms include fever, increased frequency of urine and burning micturition. UTI usually responds quickly to treatment. If not treated then there is a risk of it spreading to kidneys or to cause sepsis particularly after a major surgery.

Acute Kidney Injury

Acute renal failure can be there in any surgery in which enough fluid has not been infused intraoperatively or postoperatively. It can also be caused due to antibiotics, prolonged hypotension, obstructive jaundice, etc. It is more likely to occur in patients who are elderly, those with liver disease, having surgery to aorta and those with severe atherosclerosis. Besides conservative treatment hemodialysis may be required.

Bladder or Ureter Injury

During surgery of uterus, cesarean section, or kidney sometimes urinary bladder or ureter get damaged. Anatomical precise dissection can save this complication.

Sufferings from nonremoval of stones from kidney by operation: Sewa Ram vs Dr Vitul K. Gupta, K. P. Mission Hospital and Maternity Home, 1999 (2) CPR 68 (Chandigarh): The patient approached the doctor for treatment of acute retention of urine and suprapubic pain. He was operated upon for removal of stones from urinary bladder. It is alleged that the patient suffered from pain due to nonremoval of stone from left kidney while operating upon urinary bladder for removal of stones.

The State Commission, Punjab, did not hold the doctor negligent for conducting the operation, as it is established from expert evidence that the stones cannot be removed from the kidney while performing operation for removal of stones from urinary bladder.

Gastrointestinal System

Constipation

It is common in days and weeks after surgery, caused by anesthesia, dehydration, decreased appetite, analgesics particularly opiates and immobility after surgery. Constipation becomes difficult to treat sometimes if not attended to in the beginning. Early mobilization and swift reduction in painkillers as the pain eases shall help. Constipation should be differentiated from paralytic ileus and obstruction in which flatus is not passed.

Paralytic Ileus

In paralytic ileus bowel becomes still and loses its rhythmic contractions. It may last from few hours to few days but can last much longer. It is particularly common in cases of electrolyte imbalance, in elderly, diabetes, in patients with hypothyroidism and Parkinson's disease.

Intestinal Obstruction

Postoperatively bowel can be obstructed by twisting and by adhesions by the scar tissue specially when it is cut during surgery or an end to end anastomosis is done. Patient shall have colicky abdominal pain, nausea and vomiting. It is to be treated accordingly.

Intestinal Perforation/Leak

It can also be a complication of surgery if bowel has been resected and an end to end anastomosis has been done. Small leaks are common and cause small abscesses inside abdomen, sometime several weeks after surgery. Large perforations are less common and cause severe pain and peritonitis which is a surgical emergency to be treated accordingly after laparotomy.

Hepatobiliary System

Liver

It may get damaged during surgery of liver abscess, hemangioma liver, gall bladder, common bile duct, etc.

Common Bile Duct Injury

It is one of the commonest postoperative complications in surgery of gall bladder.

Cystic Duct and Artery

After surgery of gall bladder cystic duct ligature or cystic artery ligature may get slipped in postoperative period leading to bile/biliary or blood collection in peritoneum.

Death due to negligence in conducting cholecystectomy: Altaf Hussain Farooqui vs Dr Ashok Mathure, 1998 (1) CPR 427 (Mah): The wife of the complainant was operated for removal of stone from gall bladder by the doctor. The surgeon had put the tube for draining out the bile liquid after cholecystectomy. As the surgeon did not adopt proper course of draining out the bile liquid from time to time, the patient developed about 8000 cc of bile liquid, which was infected leading to biliary peritonitis. The patient ultimately died of septicemia.

The State Commission, Maharashtra, held the surgeon negligent in conducting cholecystectomy by not adopting proper course of draining out the bile liquid from time to time and for delay in diagnosis and giving proper treatment to the patient.

Death due to complications after cholecystectomy: Smt Asha vs Dr Santokh Singh, Proprietor, Waryam Singh Memorial Hospital and Nursing Home, 1999 CTJ 47 (CP) (SCDRC) (Chandigarh): The patient had undergone operation for removal of stone from gall bladder. The patient developed pain in abdomen. The second surgery was performed for removal of fluid accumulated in abdomen after seven days of the first operation. The operating surgeon had gone abroad leaving the patient under care of the junior doctor and ultimately the patient expired.

The State Commission, Punjab, did not hold the doctor negligent for conducting the operation, as the patient was attended by one experienced and qualified surgeon during the absence of the operating surgeon and as collection of fluid in abdomen after cholecystectomy may require second surgery.

Gossypiboma/Left Over Foreign Body

Any instrument, or mop or gauge or any other foreign body left unknowingly in abdomen has serious medicolegal repurcussiom. This is an avoidable surgical complication. The doctrine of *res ipsa loquitur* can be applied in most of the cases otherwise the surgeon has to prove that it was part of management in those circumstances. In such case corrective surgery must be performed.

Artery forceps left in abdomen after surgery: Nihal Kaur vs Director, Post Graduate Institute of Medical Sciences and Research III (1996) CPJ 112 (Chandigarh); 1998 CCJ 306 (Chandigarh): The patient was admitted on account of splenic abscess with septicemia. He had undergone operation. The patient expired after 15 days of the operation. He was cremated in his native village. A pair of scissors utilized by surgeon were collected from the last remains of the deceased. It is alleged that the patient died, because the scissors remained in the abdomen of the patient during operation.

The director of the hospital made the arguments that the instrument found in the abdomen was 'forceps', not 'scissors'. It is admitted on behalf of the hospital that 'artery forceps' and 'sponges' used to stop bleeding from the splenic bed during operation, were left inside the abdomen and the abdomen was closed in order to avoid the fourth cardiac arrest of the patient, as the patient suffered from three cardiac arrests and was revived each time during the operation.

The court held the hospital negligent in conducting the operation of the patient.

Surgical gauze left inside the body: Chanchal Oswal vs Santokba Durabhai Memorial Hospital, I (1995) CPJ 42: The complainant alleged that the opposite party had left a surgical gauze inside her chest at the time of a heart operation. The version of the opposite parties was that some fluid had collected on the left side of the chest and the complainant was advised to get it removed. The allegations could not, however, be proved by the complainant.

Held, the complainant is required to prove that the alleged surgical gauze was left inside her body at the time of the operation performed by the respondent. The subsequent medical reports do not prove this fact. They are no public documents. No independent oral evidence whatsoever has been produced by the complainant in this connection. The complainant has not referred to these documents in her complaint. The affidavit of the doctor who operated her at Bangalore, has not been submitted by her to show that he had taken out a surgical gauze at the time of the second operation. The complainant was under anesthesia at the time of the operation. Her husband was not in the theatre at the time. Surgical gauze taken out was not in the theatre at that time. Surgical gauze taken out was neither preserved nor produced nor submitted for chemical analysis. The affidavits of the medical officers who prepared the discharge certificate, operation note, and other reports have not been filed. In the discharges summary, card-columns diagnosis and finding contained in the operation notes do not show that the gauze had been left inside the body of the complainant. It is firmly established that when a person undergoes surgical operation, there is inherent risk and likelihood postoperative complications. There is not the slightest evidence of any deficiency in service and consequent negligence of the respondent when he performed the operation of the complaint. Complaint dismissed

Gynecology and Obstetrics

Common complications are:

- Injury to large vessels such as vena cava, internal iliac vein and common iliac artery.
- Damage to ureter and bladder.
- Ureterovaginal and vesicovaginal fistulae.
- Hemorrhagic and hypovolemic shock.
- Thrombosis and subsequent embolism, DIC.

Damage due to improper D&E operation: Vinubhai Parsottamdas Patel vs Dr Vijay Kumar Ajmera, 1997 (1) CPR 348 (Guj.): The patient had undergone D&E operation for termination of pregnancy. She developed pain in abdomen and suffered from fever, nausea and vomiting during postoperative period. As the condition of the patient deteriorated, she was shifted to better equipped hospital where the doctor opined that there were perforations in the uterus and intestine and that pus had collected in the abdomen. The patient was operated and after improving the condition of the patient another operation for 'fecal fistula' was performed on the patient.

It is held by the State Commission, Gujarat, that the patient suffered physical pain and mental agony due to negligence on the part of the doctor in performing D&E operation.

Sufferings due to complications after medical termination of pregnancy: Dr C.V. Mathew vs P. Babu, 1999 (3) CPR 461 (Ker); I (2000) CPJ 134 (Ker): The patient had

undergone, MTP and PPS under the care of the doctor, she developed pain in the stomach and vomiting and the medicines prescribed by the doctor did not work. The patient was shifted to Medical College Hospital where some portion of foetus left in uterus of the patient, was evacuated after about 7 weeks of MTP conducted by the doctor.

The State Commission, Kerala, held the doctor negligent not for complications developed after D&C, but for not making any attempt to ascertain the reasons of ailment when the patient complained of pain and vomiting.

Postoperative care—delivery of child—surgery of LSCS: Sayed Mohmmed Owais Quadri and others vs Dr Neena Desai and others 2002 (3) CPJ 52 (AP): Allegations negligence in performing LSCS of wife of the complainant and in rendering post-operative care—medical literature to the effect that as a rare phenomenon DIC may occur, PIH and DIC resulting in cardiorespiratory arrest—this phenomenon is a sudden complication which may arise at any time of delivery—bleeding from mouth and nose also noticed which cannot be due to negligence of surgery of LSCS—no evidence clearly pointing out any deficiency in service on the part of OPs—complaint dismissed.

Vesicovaginal fistula: Dr Rameshwar Pd. Agrawal vs Md. Abas Ansari (SCDRC) BHR 2000-(001)-CPJ-0433: VVF is a known complication. Many fistulae develop after gynecological operations. As appellant result from injury to the bladder during hysterectomy. Damage may not be recognised at the time of operation. Fluid was observed in cul-de-sac in ultrasonography before the operation which may have been possible because of leakage in the bladder. However, the source of fluid in cul-de-sac was because of some hole in the urinary bladder from before is not established. Reasonable to assume that VVF occurred during removal of uterus. Wound was closed in layers and indwelling catheter was placed in urethra which was removed after ten days. Hence, the act of doctor cannot be held as negligence.

Cesarean Section and Hysterectomy: K. Gracykutty vs Dr Annamma Omnem: 1992 (1) CPR 251 (Kerala): The allegation was that in the management of second delivery of the patient through cesarean operation the doctor carelessly cut the internal iliac arteries of the patient leading to heavy bleeding and performed unwarranted and inexpert hysterectomy causing damage to the bladder and vaginal fistula.

The complaint was dismissed by the State Commission, Kerala, because the views expressed by the expert had prompted the commission to infer that the doctor had exercised reasonable standard of care and competence in handling this case and had acted in accordance with the general and approved practice of the profession.

Orthopedics

Common complications are:

- Deep infections, osteomyelitis.
- Thromboembolism.
- Joint instability and dislocation.
- Arterial injury.
- Nerve injuries.
- Periprosthetic fractures, specially with THA and TKA.
- Complex regional pain syndrome.
- Acute compartment syndrome.

Fractured left hip—left leg shortened: Bhavchandbhai Manjibhai Lakhani vs Bhupendra D. Sagar, I (1994) CPJ 361 (Gujarat): The complainant was admitted in nursing home for treatment of fracture to left hip caused by accident. The operation was performed by doctor under general anesthesia. The patient felt pain at the place of operation. Subsequent X-ray revealed that the bone was not properly fixed and thereby left leg shortened by 2.5 inches. The complainant claimed compensation from the doctor for negligence in performing the operation of the neck of the femur. It was held by the State Commission, Gujarat, that the operation failed because of the negligent manner in which the operation was performed by the doctor.

Fixing of plate and bone grafting: Sardool Singh vs. Munilal Chopra and another, SCDRC, PUN, 1999-(001)-CPJ-0064: Appellant/Complainant → Fractures in legs due to accident → brought to the hospital of the opposite parties → right leg operated → plate fixed and bone grafting done → subsequently left leg was likewise operated → discharged → plates in one of the legs were broken → attributing negligence filed complaint → dismissed → appeal → dismissed.

Fracture—subsequent operation by an other doctor: Inderjeet Singh vs Dr P.K. Bhatia and another, 1998 (3) CPJ 289 (Haryana SCDRC): The complainant suffered an accident in which both bones of his left arm were fractured, for which he remained as indoor patient with Dr Bhatia for 13 days. Since the infection of his wound did not subside, he got operated again by Dr P.S. Maini of the Sir Ganga Ram Hospital, New Delhi and incurred heavy expenditure. The State Commission held that simply because a subsequent operation was required does not prove negligence in treatment and upheld the decision of District Forum and dismissed this appeal.

Amputation of left hand due to defective plaster cast: Naushad (minor) vs Koyili Hospital, Kannur, 1996 (3) CPR 367 (Ker): The patient sustained fracture on left hand and was taken to the hospital for treatment. The patient was put on plaster and advised to come after two weeks for removal of plaster. The patient developed high fever and severe pain in the plastered hand. There were blebs on the fingers and the nail beds were blue and the fingers were cold. The plaster was removed, but the condition of the patient deteriorated. Ultimately the left hand of the patient had to be amputated. The patient claimed compensation against the doctor.

The State Commission, Kerala, dismissed the complaint, because it was established from expert evidence that there was no effective means of active immunisation against clostridial myonecrosis or gas gangrene and that there was no evidence to indicate that gas gangrene developed on account of any defect in the treatment.

Ophthalmic Surgery

Common complications are:

- Postoperative capsular ossification.
- Raised intraocular pressure.
- Corneal decomposition.
- Cystoid macular edema.
- Retinal detachment.
- Endophthalmitis.

Injury to cornea and left eyeball due to defective operation: Jaswinder Singh vs Dr J.S. Saini, II (2000) CPJ 262 (Chandigarh): The complainant aged 6 years was born

with ptosis, i.e. drooping of left eyelid. The patient had undergone operation under the care of the surgeon in PGI, Chandigarh. There was further drooping of eyelid instead of lifting of the same after the operation. The patient suffered a serious damage to the tear gland resulting in nonformation of tears. It is alleged that surgeon caused injury to the left eyeball and cornea of the patient by negligent performance of the operation, resulting in double vision and permanent disability.

It is held by State Commission, Chandigarh, that the surgeon was negligent.

Loss of eyesight after cataract operation: Kailash Kumar Sharma vs Dr Hari Charan Mathur, 1997 (2) CPR 126 (NC): The patient was operated in one of his eyes for cataract and intraocular lens was implanted by the doctor. It is alleged that the patient lost vision in the operated eye due to negligence of the doctor in conducting the operation.

The State Commission, dismissed the complaint as there was no iota of evidence to substantiate the contention that loss of vision was due to improper implantation of IOL or negligence of the doctor to conduct the operation. The order of the State Commission was confirmed by National Commission, on appeal.

Loss of eyesight after glaucoma operation: Mrs Asha Rani vs Dr Rohit Grover, 1997 (1) CPR 55 (Chandigarh); III (1996) CPJ 259 (Chandigarh); 1998 CCJ 100 (Chandigarh): The patient was operated for glaucoma in left eye, but her eyesight did not revive. She was examined by the surgeon on five occasions after her discharge from the hospital and she was operated upon thrice on her left eye, but these were of no avail.

The State Commission, Chandigarh, did not hold the surgeon negligent, as the complainant failed to adduce evidence to prove negligence on the part of the surgeon.

ENT

Common complications are:

- Local trauma from surgery.
- Scarring from skin incision.
- Bleeding, primary or secondary.
- Failure to improve.
- DVT/pulmonary embolus.
- Complications related to specific procedures.

Postoperative care—hearing impairment. Ashok Nandi vs Dr Ajit Saha and another, 2003 (4) CPJ 95 (WB): Allegation of deficiency in service on the part of OP in the matter of treatment and surgery of right ear → that no postoperative care was taken resulting in defness → no medical expert brought into substantiate the allegation → if the operation is not successful that does not mean that the surgeon was negligent and careless → cannot be held that operation was conducted hastily → no negligence.

Disability after thyroidectomy: Mrs S. Jaiboon vs Dr S.S. Reddy, Surgeon, Hyderabad Nursing Home, 1998 CTJ 290 (CP) (SCDRC): The patient had undergone thyroidectomy operation. The patient developed breathing trouble, and snoring sound in breathing and her normal speech was affected. The ailments were diagnosed as vocal cord paralysis for which she had to undergo "woodman's operation". It is alleged that the patient suffered from disability and trouble and unnecessary expenditure due to negligence of the doctors.

The State Commission, Andhra Pradesh, did not hold the doctor negligent, as there was no expert evidence to indicate that "bilateral abductors paralysis" of the patient was due to deficiency in service on the part of the doctor in conducting thyroidectomy, particularly when standard medical literature points out that vocal cord paralysis may be the result of thyroidectomy.

Discharge from left ear: A. Sambi Reddy vs KKR, ENT Hospital and Research Institute and another (SCDRC) TN, 1999-(001)-CPJ-0165 SCTN: Complainant → father of the deceased → patient used to have discharge of a watery liquid from his left ear → consulted opposite party → found small hole in the ear → advised plugging and minor operation → operation conducted → entered coma stage during operation → shifted to another hospital → informed that damage to brain has occurred → referred to railway hospital → later patient died → alleging negligence filed complainant claiming, compensation of Rs 9,00,000. Dismissed.

Common Preventive Measures for Postoperative Complications

- Weight control
- Nutritional health
- Quitting smoking
- Anemia correction
- Minimization of blood loss during surgery
- Fluid volume to maintain blood pressure during surgery
- Electrolyte balance
- Judicious use of antibiotics
- Technique of incision
- Prudent analgesia
- Early mobilization
- Physiotherapy
- Preoperative evaluation for patient fitness.

MEDICOLEGAL ISSUES

Postoperative complications after any surgery are well documented in the scientific medical literature. It is important to differentiate whether the complication that occurred was unavoidable or due to some negligence. Negligence in rendering service is more serious than deficiency in rendering service, deficiency is an expression of wider import than negligence. An act or omission, which may not amount to negligence, may amount to deficiency in service. Every mistake by surgeon cannot be regarded as negligence or deficiency.

Duties of Doctor

A duty of care in deciding whether to undertake the case, a duty of care in deciding what treatment to give. A duty of care in the administration of that treatment, breach of any of their duties—right of action for negligence arise.

Degree of Skill and Knowledge

Skill of medical practitioner may differ from doctor to doctor negligence cannot be attributed if doctor has performed his duties to the best of his ability and with due

care and caution and acceptable to the medical profession. Doctors must exercise a reasonable degree of care. Degree expected is neither the very high nor very low. Must be just and fair in the light of the particular circumstances of each case.

Test of Medical Negligence

One of the tests of medical negligence is that something which is required under medical practice to be done was not done or what was done was contraindicated.

The judicial conscience is that where the medical practitioner discharges his duties to the best of his ability, it would not constitute negligence or deficiency in service. If operative notes mention that a thorough lavage was done at the wound site to remove debris, it will be indicative that due care was provided by the surgeon. Similarly, if a pack is left inside abdomen to maintain homeostasis deliberately to plan another procedure afterwards, it is not negligence. It is advisable to inform to attendants for the same and record in the case sheet. Lack of information and documentation would lead to blame of negligence.

Almost all surgical complications can lead to a second procedure. Timely recognition and management of complication do not come under preview of negligence if the complication is known in medical literature and due informed consent was taken before first procedure. Appropriate counseling of the patient and attendants with discussion about possible management and outcomes would act as a litigation prevention strategy. Having a second opinion helps in restoring surgeon's as well as patient's confidence.

A surgeon can come across a patient who has been previously operated by some other surgeon. If a surgeon find some negligent act during second surgery, e.g. forgotten mop, it is his legal duty to inform the patient. If a surgeon is called by another surgeon for intraoperative or postoperative complication, the surgeon called is legally bound to inform patient and attendants about any negligent act. Sometimes, it becomes a tricky situation when the second surgeon has to handle the complication safeguarding first surgeon and satisfying attendant. Very intelligently one should keep the balance between first surgeon and attendants to diffuse the tension and avoid any litigation.

CONCLUSION

There have been great advances in the science and its application to surgery but the art of surgery still has an important role. Surgeon should review occasionally the basic principles upon which the successful outcome of all surgical procedures depends. Moreover for the least postoperative complication there must be a happy marriage of the science and art. The science is taught but the art comes with experience and learning.

REFERENCES

1. Matsen F. Winquist R. Krugmire R. (1980) Diagnosis and management of compartmental syndrome, *J. Bone Joint Surg* 62A: 286
2. Rader CP, Barthel T, Haase M. Heterotropic ossification after total knee arthroplasty: 54/615 cases after 1–6 years follow up. Acta Orthopaedic Scandinavia 1997;68:46–50.
3. Shoenfield NA, Stuchin SA, Pearl R. The management of vascular injuries associated with total hip arthroplasty *J. Var Sur* 1990;1:549–55
4. Della Valle CJ. Zukerman JD, Di Ceasre PE. Periprosthetic sepsis Cl, *Orthop Rel Res* 2004;420: 26–31.

5. Mersky H. Bogdesk. N (1994) Classification of chronic pain description of chronic pain syndromes and definition of pain terms, Second Edition. International Association for Study of Pain Press: Seattle.
6. Geerts WH Heit JA, Clagett GP. Prevention of venous thromboembolism. Chest 2001;119:132S–175S.
7. Schmalzried TP, Amstutz HC, Dorey FJ. Nerve Palsy associated with total hip replacement, Risk factors and prognosis. *J. Bone Joint Surg* 1991;73A:1074–1108.
8. Dr. Mary Lowth. Reviewed by Dr Adrian Bonsall "Common Postoperative Complications" edition July 2017.
9. Turpie AG, Chin BS, Lip GY. Venous Thromboembolism: Pathophysiology, Clinical features and presentation. *British Med J* 2002;325:887–90.
10. Wheeles lr CR. Atlas of Pelvic Surgery, 3rd cd. Baltimore: Willams and Wilkins; 1997: 492–7.
11. Raut V. Shrivastava A, Nandanwar S. Bhattacharya M. Urological injuries during obstetric and gynaecological procedures. *J Postgrud Med* 1991 Jan: 37(1):21–23.
12. Herowietz IF. Postanesthesia and postoperative care. In : Te Linde's Opretive Gynecology, 8th ed. Rock JA, Thompson ID eds. Philadelphia Lippincott Raven Publishers 1997:140–42.
13. Smith HO, Shock in the gynaecological patient, In: Te Linde's Operative Gynaecology, 8th edn. Rock JA, Thompson JD (eds), Philadelphia: Lippincott Raven Publishers; 1997:245–55.
14. Hager WD. Postoperative infections prevention and management. In: Te Linde's Opretive Gynecology.8th ed. Rock JA, Thompson ID (eds). Philadelphia: Lippincott Raven Publishers 1997:233–38.
15. Surgical Technology for the Surgical Technologist: A Positive Care Approach. Caruthers BL, et al (eds). Albany, NY: Delmar Thomson Learning, 2001.

Section

3

Errors in Practice and Unexpected Outcome

13. Unexpected Blood Transfusion Reactions
14. Medication Errors
15. Mistakes by Staff
16. Equipment Failure and Faulty Medical Devices
17. Unexpected Congenital Anomalies/Birth Asphyxia

Section Editors: Arun Manglik, Subhendu Dey

Chapter

13

Unexpected Blood Transfusion Reactions

Amit Shandilya, RK Maheshwari

INTRODUCTION

Blood transfusion is the transfer of blood or blood products from one person (donor) into another person's (recipient) bloodstream. This is done as a life-saving procedure to replace blood cells or its products. It also helps if an illness prevents body from making blood or some of blood's components correctly.

TYPES OF BLOOD TRANSFUSIONS

Blood transfusion could be a broad term which include transfusion of blood or its various products[1] as listed below and compared in Table 13.1

- Whole blood transfusion
- Blood cells transfusion (cell transfusion)
  a. Packed red cell transfusion or red cell concentrate
  b. Leukoreduced RBC
  c. Granulocyte transfusion (given in cases of severe neutropenia)
  d. Platelet transfusion
- Plasma transfusion
- Plasma derivatives
  a. Fresh frozen plasma
  b. Cryoprecipitate
  c. Albumin
  d. Coagulation factors concentrate
  e. Immunoglobulins (Ig)

MANDATORY TESTS FOR GIVING BLOOD TRANSFUSION

First of all, ABO-Rh blood group is determined. The donated blood used for transfusion must be compatible with blood group of recipient. A and B are different antigens on the surface of red cells. 'O' blood group persons do not have either antigen, whereas AB blood group persons have both antigens on their red cells. Blood is classified into group Rh positive or Rh negative on basis of presence and absence of 'D' antigen on RBC. Only 5% Indian population is said to be lacking in the D antigen (Rh –ve) (2, 3).

Table 13.1: Comparison of blood and its various products

	Whole blood	*Red cell concentrate*	*Platelet transfusion*	*Fresh frozen plasma (FFP)*	*Cryoprecipitate*
Composition	Donor blood mixed with an anticoagulant	Most of plasma is removed and replaced with a solution of glucose and adenine in saline to maintain viability of red cells	Mainly platelets, some non-functional WBCs, a few RBCs and plasma	Plasma, all coagulation factors, albumin and Ig	Contains factors VIII (very rich), fibrinogen as well as factor XIII and von Willebrand factor (WWF)
Procedure for collection	Venesection	Blood to separate by gravity or by special refrigerated light centrifuge	Plateletapheresis	By product left after second heavy centrifuge and removing of supernatant platelet-rich plasma	Supernatant precipitate of FFP
Storage	1–6°C	2 to 6°C	20–24°C with agitation	–40 to –50°C	– 40°C
Shelf life	Up to 5 weeks	120 days Cryopreservation of RBC up to 10 years	5 days	Up to 1 year	Up to 2 years
Advantage	Simple Inexpensive No special instrument required for processing Rich in coagulation factors If fresh, metabolically more active than stored blood	Easy to prepare Avoids volume overload Less adverse effects Less immunosuppressant	Controversial role in thrombocytopenia like dengue, idiopathic thrombocytopenic purpura (ITP), sepsis	It is an acellular component so no chance of transmission of intracellu lar infections Used to prepare immunoglobulin Therapeutically use to increase plasma protein	Rich in factor VIII, factor XIII and fibrinogen Used to treat uremic bleeding when other modalities have failed
Disadvantage	Risk of circulatory overload Storage leads to loss of platelet and coagulation factors Narrow shelf life	↑ viscosity ↑ time required to pass through cannula and vessels	Short lifespan Platelet aggregation Bacterial contamination	Once thawed should be immediately used Efficacy maintained by coagulation testing prothrombin time (PT), APTT, INR	Cryoprecipitate is deficient in all clotting factors other than fibrinogen, factor VIII, and factor XIII

The various mandatory tests besides blood grouping (ABO and Rh) to be done before clearing the blood for transfusion into recipient are:

- VDRL test
- Hepatitis A, hepatitis B (HBsAg) and hepatitis C.
- HIV antibodies screening.
- Test for malarial parasite

If any test is positive, the blood must be discarded.

Criteria for Donor

- Normal body temperature, blood pressure
- Weight above 50–55 kg and age 18–55 years
- Normal hemoglogin (Hb) levels.
- Free from RTI, skin disease
- No h/o drug addiction
- No h/o viral hepatitis
- No HIV infection or risk for it
- No h/o blood transfusion (<= 6 mo)

ADVERSE REACTIONS TO BLOOD TRANSFUSION

Though, all blood banks take proper precautions to make blood transfusion as safe as possible, but still some or other adverse reactions do occur. Adverse reactions may occur in donor as well as in the recipient.

Adverse Reactions in Donor

- Psychological effects
- Hyper-/hypotension
- Mild symptoms, e.g. fever, nausea, vomiting, giddiness
- Entry of infection if bleeding site is not cleaned or use of unsterilized needle or instruments.

Adverse Reactions in the Recipient

In spite of modern techniques to supply blood or its products quite safe, adverse reactions do occur with both whole blood and blood products. These reactions can be same whether whole blood transfusion is given or its components are given but still some adverse effects are more likely to appear in a particular section. These reactions can be classified in various ways, e.g. acute or delayed (Table 13.2) or as per their etiology.

Table 13.2: Types of blood transfusion reactions

Acute transfusion reactions	*Delayed transfusion reactions*
Acute hemolytic reaction (AHTR)	Delayed hemolytic transfusion reaction (DHTR)
Anaphylaxis	Transfusion transmitted infection
Bacterial contamination of blood component	Transfusion-associated graft-versus-host disease (GVHD)
Transfusion-related acute lung injury (TRALI)	Post-transfusion purpura
Transfusion-associated circulatory overload (TACO)	Iron overload
Allergic reaction	Immunosuppression
Febrile nonhemolytic transfusion reaction (FNHTR)	

The adverse reactions can also be classified as per their etiology as follows:

- **Infectious:** Bacterial/viral/parasitic infections
- **Non-infectious (usually immunological):**
  - Reactions to RBC antigens (acute hemolytic transfusion reactions or AHTR, delayed hemolytic transfusion reactions (DHTR)
  - Reactions to donor proteins (anaphylaxis, allergic reactions)
  - White cell-related transfusion reactions (e.g. febrile reactions, transfusion-related acute lung injury or TRALI)
- **Volume overload:** Transfusion-associated circulatory overload (TACO)
- **Electrolyte imbalance:** Citrate toxicity/hypocalcemia/hyperkalemia and hypothermia due to rapid transfusion of refrigerated cold blood.
- **Others:** Air embolism, hemochromatosis, Rh incompatibility

Infectious or Non-immunologic Reactions

These reactions are usually caused by the physical effects of blood components or the transmission of disease. The likelihood of contracting infection from blood transfusions is very low (varies with infectious agent from 1 in 35000 to 1 in 1 million)

a. **Bacterial:** Blood could be contaminated by bacteria (e.g. *Treponema pallidum,* Staphylococci, Streptococci) or bacterial byproducts (such as endotoxin) and may cause septic transfusion reactions. Source of infection could be donor, unsterilized IV set, needles, etc. Bacterial infections are more common with platelet transfusions.
b. **Virus** (e.g. hepatitis A, B, C virus, retrovirus, herpesvirus, parvovirus)
c. **Parasites** (e.g. *Trypanosoma cruzi, Babesia microti, Leishmania donovani, Plasmodium*)

Non-infectious (Usually Immunological)

Immune-mediated transfusion reactions typically occur due to mismatch or incompatibility of the transfused product and the recipients. These include naturally occurring antibodies in the blood recipient (such as anti-A, anti-B which are typically responsible for acute hemolytic transfusion reactions) as well as antibodies made in response to foreign antigens (alloantibodies) which account for many reactions including mild allergic, febrile non-hemolytic, acute hemolytic and anaphylactic shock.[4–6] Antibodies present in the blood donor can also cause reactions and are thought to be involved in transfusion-related acute lung injury (TRALI). The various immunological adverse reactions are acute hemolytic transfusion reaction, anaphylaxis, minor/major allergic reactions, febrile reactions, TRALI, etc.

Reactions to RBC Antigen

- **Acute hemolytic transfusion reactions (AHTR):** Acute hemolytic transfusion reaction is a serious complication that can occur after a blood transfusion either immediately or within 24 hours. The reaction occurs when the transfused red cells are destroyed (hemolysis) by the recipient's immune system. It is said to be due to binding of donor red cell antigens with recipient antibodies to form immune complexes resulting in hemolysis and disseminated intravascular coagulation (DIC) leading to intra- or extravascular hemolysis. Nonimmune reactions are possible and can occur when red blood cells are damaged before transfusion (e.g. by exposure to heat or in faulty osmotic conditions).

- **Delayed hemolytic transfusion reaction:** Typically caused by an anamnestic response to a foreign antigen that the patient was previously exposed to (generally by prior transfusion or pregnancy).

Reactions to Donor Proteins

- **Allergies:** Allergic reactions are common. In fact, according to the CDC, allergic reactions make up over 50% of reported reactions to blood transfusions. They can manifest as:
  a. Minor or localized reactions: Flushed skin, morbiliform rash, angioedema, periorbital itch, conjunctivial edema, minor edema of lips and tongue.
  b. Moderate reactions: Cough, hypotension, tachycardia, dyspnea, loin pain angina and anxiety.
  c. Life-threatening reactions: Severe hypotension, shock, wheezing, stridor, change in voice, severe anxiety.
- **Anaphylaxis:** This happens within minutes of starting a transfusion and may be life-threatening. Such reactions, though rare, occurs in an individual who previously had been sensitized to an allergen present in the blood and, on re-exposure, releases immunoglobulin E (IgE) or IgG antibodies. It is also seen in IgA-deficient patients who have anti-IgA antibodies. Patients with anaphylaxis become acutely dyspneic due to bronchospasm and laryngeal edema and may complain of chest pain, abdominal pain and nausea.

White Cell-related Transfusion Reactions

- **Febrile non-hemolytic transfusion reaction (FNHTR):** Fever and chills during transfusion are thought to be caused by recipient antibodies reacting with white cell antigens or white cell fragments in the blood product or due to cytokines, which accumulate in the blood product during storage.
- **Transfusion-related acute lung injury (TRALI):** It is a rare but serious complication characterized by sudden acute respiratory distress following transfusion. It is defined as new, acute lung injury (ALI) during or within six hours after blood product administration in the absence of temporarily-associated risk factors for ALI.[7] All plasma-containing blood products have been implicated in TRALI. In most of the cases it is thought to be caused by activation of recipient neutrophils by donor-derived antibodies targeting human leukocyte antigen (HLA) or human neutrophil antigen (HNA). Patient presents with the rapid onset of respiratory distress (dyspnea and tachypnea), cyanosis and hypotension and sometimes fever. Mortality rate is as high as 20%.
- **Transfusion-associated graft-versus-host disease (GVHD):** This complication is extremely rare, but is usually fatal. The incidence is <2% but the mortality is > 75%. It happens when the white blood cells in the new blood attack bone marrow.[8] This reaction is more likely to occur in persons with a weakened immune system. As a result patient's immune system is not able to clear the foreign lymphocytes and the donor lymphocytes (which are immune-competent) recognize the patient as foreign and react against the recipient's body and starts killing the host cells. Manifestations of GVHD can be hyperacute, acute or chronic.

Transfusion-associated Circulatory Overload (TACO)

Transfusion-associated circulatory overload (TACO) occurs when the volume of the transfused component causes hypervolemia (volume overload). This entity is usually seen in patients who are in ICU/hospital for a prolonged duration. Cases can be minimized by keeping an eye on fluid intake/output and rate of transfusion.[9]

Electrolyte Abnormalities

Serum potassium, calcium and magnesium may be disregulated with massive transfusion.

- **Citrate toxicity and hypocalcemia:** Sodium citrate is used as an anticoagulant during blood collection. Citrate toxicity usually appears after massive blood transfusion and presents as metabolic alkalosis. Citrate gets converted into bicarbonate and causes alkalosis. It also chelates calcium and leads to hypocalcemia. This may manifest as tetany, decreased myocardial contractility and hypotension.[10]
- **Hyperkalemia:** This is also seen after massive transfusions. During normal storage K^+ ions are leaked from red cells. It reaches equilibrium with the potassium level of the anticoagulant or preservative solution, allowing for an increase in the biologically active extracellular potassium pool leading to cardiac arrest. Potassium levels as high as 70 mmol/L have been reported in the supernatant of RBC units, that had been stored for the maximum allowable time.
- **Hypothermia:** Rapid infusion of large volumes of stored refrigerated blood contributes to hypothermia. Infants are particularly at risk during exchange or massive transfusion. Appropriately maintained blood warmers should be used during massive or exchange transfusion.
- **Hypomagnesia:** Prolonged QT interval with hypomagnesemia is a potential serious complications.[11]

Others

- **Air embolism:** An air embolism, also called a gas embolism, occurs when one or more air bubbles enter a vein or artery and block it. When an air bubble enters a vein, it is called a venous air embolism. When an air bubble enters an artery, it is called an arterial air embolism. These air bubbles can travel to brain, heart, or lungs and can cause heart attack, stroke or respiratory failure. Air embolisms are rather rare.
- **Hemochromatosis (iron overload):** Persons receiving repeated or multiple blood transfusion may suffer from iron overload which may damage heart, liver.
- **Rh incompatibility:** There is possibility of transfusion of Rh +ve blood to Rh –ve individual. The first transfusion of the Rh ±ve blood causes the development of anti-Rh agglutinins in the serum, so that a subsequent transfusion of Rh +ve blood may produce an incompatibility reaction exactly similar to that which occur when group A blood transfused into a group B person, namely hemolysis of the incompatible blood cells and possible jaundice or hemoglobinuria. This reaction can be mild, severe or even fatal.

GRANULOCYTE TRANSFUSION (GTX)

Granulocyte transfusions have been used to treat and prevent infections (both bacterial and fungal) in neutropenic patients, despite persistent controversy regarding their efficacy. The usual method to obtain granulocytes for transfusion is by single-donor apheresis.[12]

Complications

- Fever: Mild fever has been reported in patients (17.5–41%).
- Human leukocyte antigen (HLA) sensitization: Recipients may develop antibodies against HLA antigens and antineutrophil antibodies (against non-HLA antigens). Incidence as high as 70% has been reported.
- Pulmonary reactions (manifested as pulmonary infiltrates and hypoxemia) are seen mostly in cases where amphotericin B is simultaneously used.
- Cytomegalovirus (CMV) infection is a possibility if CMV positive donor is used. Hence, it is better to go for a CMV negative donor.

PLATELET TRANSFUSION

Platelet transfusion can be random donor platelets (RDP) or single donor platelets (SDP).

Platelet transfusions are contraindicated in autoimmune thrombocytopenia and thrombotic thrombocytopenic purpura and related syndromes. It should also be avoided in heparin-induced thrombocytopenia and DIC. Donor criteria are the same as above but there should be no history of ingestion of salicylates or nonsteroidal anti-inflammatory drugs in past 7 days.

Platelet concentrates have a short shelf life (approx 5 days). Attempts are on to increase the shelf life of the platelet concentrates and maintain their function by addition of synthetic additive solutions. The advantages of these nonplasma storage media are prevention of lactate accumulation, removal of products like complement, kallikrein, thrombin and plasmin and removal of platelet microvesicles.

The adverse reactions are immunological reactions or infections. Transfusion reactions vary from FNHTR to allergic reactions.

Immunological

1. Allergy (itching/rashes) or anaphylaxis (fortunately rare).
2. GVHD
3. Platelet refractoriness: It is labeled when there is less than expected rise in platelet count.
4. Post-transfusion purpura (or PTP): More than 90% cases of PTP are females HPA1b and have developed anti-HPA1a antibodies due to immunization in previous pregnancy.
5. Infection
   a. The risk could be as high as 1:2000 and the mortality rate is as high as one in four.
   b. Bacterial infections are more common with platelet transfusion than whole blood transfusion. This could be because of the fact that platelets are stored at 20–24°C (whole blood stored at 1–6°C).

c. Viral infections (HIV, HBV, HCV) can also be transmitted. Many authors have reported new viruses transmitted by platelet transfusion.
d. Some unscreened pathogens may also be transmitted.[13,14]

Fresh Frozen Plasma (FFP)

FFP is the fluid portion of one unit of human blood that has been centrifuged, separated and frozen solid at –18°C or below within 8 hours of collection. It should be transfused within 24 hours after thawing and during this period it should be stored at 1–6°C. It must be ABO compatible with recipient RBCs. FFP is contraindicated for the reversal of anticoagulation induced by heparin, direct thrombin inhibitors, or direct factor Xa inhibitors because FFP does not effectively reverse anticoagulation induced by these medications. Adverse effects are more or less the same as we see with whole blood transfusion but here citrate toxicity should be kept in mind. The maximum concentration of citrate in whole blood products is present in FFP and platelets and not in packed red blood cells. Treatment includes calcium administration.[15]

Dose and Rate of Blood and its Component for Transfusion

The dose and rate of transfusion must be decided before transfusion (Table 13.3), so as to avoid overload, etc.

Table 13.3: Dose and rate of transfusion of blood/blood products

Blood/component	*Dose*	*Rate*
Whole blood	15–20 ml/kg	5 ml/kg/h
PCV	10–15 ml/kg	5 ml/kg/h
Platelet	<15 kg: 10–20 ml/kg >15 kg: Complete aphersis from single donor 1 unit/10 kg of adult	10–20 ml/kg/h
FFP	12–15 ml/kg	10–20 ml/kg/h

Adverse Reactions due to Increase Dose

1. Hemochromatosis/iron overload
2. Hyperkalemia
3. Citrate toxicity
4. Increased fluid load or retention/congestive cardiac failure (CCF)

Adverse Reactions due to Increase Rate

1. Hypothermia
2. CCF
3. Febrile reactions
4. Anaphylactic reactions

Causes of Transfusion Reactions

- Clerical errors:
  - Inadequate labeling
  - Wrong blood issued

- Technical errors:
  - Errors in blood grouping and crossmatching
  - Incorrect interpretation of test results
- Others:
  - Blood contamination during phlebotomy
  - Blood infusion through small bore needle
  - Blood cooled to –30°C or warmed to >42°C
- Concomitant administration of blood and drugs through common set.

RESPONSIBILITIES OF DOCTOR

Duty of Doctor in Blood Bank

1. Always take an informed consent, i.e. the person must be explained benefits as well as adverse effects/risks of the process. Consent must be written, documented and preferably be witnessed. It should preferably in donor's own handwriting and in his own language and if donor is illiterate, then his nearest available relative who is literate.[16]
2. He must record temperature, pulse, blood pressure (BP) (both before and after donation), respiration, skin infection at site of collection blood. All findings to be documented.
3. Doctor must follow strictly the protocol laid down.
4. Donated blood must be properly stored as per protocol
5. Preformed questionnaire related to age, height, previous medical history, any surgery in last 6 month, tattooing, any dental procedure, jaundice, infectious disease like malaria, STD, history of blood transfusion and blood transfusion reaction, etc. must be filled in pretested/prescribed proforma. Family history of repeated blood transfusion should also be recorded.
6. Label must mention date of collection and date of expiry as well as blood group.
7. Donor information must not be shared without proper consent.
8. All emergency pieces of equipment like oxygen cylinder, emergency drugs, BP instrument, etc. must be available in blood bank, so that if any adverse reaction appears in donor, it can be immediately dealt with properly.

Duty of Doctor in the Ward

1. Consent must always be taken from the recipient before starting transfusion keeping in mind all points described above.
2. Blood sample sent for grouping and matching, should be properly labeled and this fact should be recorded in the case file. Request for the blood requirement should preferably be on the proforma of the blood bank or of the institution and all the details should be filled correctly.
3. Always keep the records that from where blood for transfusion was obtained grouped and matched.
4. Check the label properly for blood group and see that this is meant for that particular patient only.
5. Do not administer blood and drugs through a common administration set or inject drugs into blood bag or use a small bore needle for blood transfusion.

6. Rate of transfusion and previous history of fluid given must be noted. This is to avoid circulatory overload.
7. Blood bag should be brought to room temperature before starting the transfusion.
8. In case of blood transfusion reactions always treat promptly and document all the treatment of the patient. Attending clinician/nurse must be aware of all the sign/symptoms of adverse blood reactions.
9. Always inform the blood bank in case of adverse reaction along with sign and symptoms of the patient.
10. All emergency pieces of equipment like oxygen cylinder, emergency drugs, BP instrument, etc. must be available in ward—so that if any adverse reaction appears in patient, it can be immediately taken care of.
11. In case of death do not panic and always inform the police and keep the patient's record securely.

When to Stop Blood Transfusion

Vital signs must be monitored and recorded at 15-minute intervals. Transfusion to be stopped if:

- Changes greater than following appear
  - $\pm$ 0.5°C in temperature,
  - $\pm$ 5 respirations per minute,
  - $\pm$ 10 beats per minute in the heart rate, and
  - $\pm$ 20 mm Hg in blood pressure.
- Hives/rashes in >25% body with or without itching
- Dark urine or decreased urine output
- Rigors: Usually denote infections
- Hypocalcemia, acidosis, hyperkalemia

If hives/rash cover <25% of body and are without any other sign/symptoms than it is a minor reactions and may not necessitate cessation of transfusion. Similarly, a rise in temperature of 1° if not associated with any other sign/symptoms is considered a minor reaction.

Responsibilities of Hospital and Blood Bank

- The hospital must ensure that all staff in blood bank and wards are properly qualified and are well versed with their jobs.
- The hospital must also ensure that all pieces of equipment are in proper shape and are well maintained and in case of instrument failure, alternative instruments are available.
- The hospital must ensure that blood from blood bank to ward is transferred in a proper way.
- SOPs must be made and properly displayed at appropriate places.
- Blood banks must be regularly sanitized.
- Random check

Responsibilities of Patient and Donor

- The donor must give all necessary details correctly. He/she must not hide anything.

- He/she must report any adverse reactions immediately.
- Donation should not be done due to economical reason.
- Preformed questionnaire should be correctly filled.

Legal Issues in Transfusion Medicine

- Licensing of blood banks: All blood banks who issue blood for transfusion must have a proper license from the appropriate authority.
- Proper administration of blood includes right patient, right dose, right product, right time, right site, with right indication along with right communication, education, and right documentation.

MEDICOLEGAL CASES

Huma Hospital vs Saleem Ansari, State Consumer Redressal Commission, UP, 1203/2006:[17]

- Mr Saleem Ansari got his daughter Rani admitted in Huma Hospital. The treating doctor advised blood transfusion. Patient was of B+ group. The father purchased blood from a blood bank and gave it to hospital for transfusing to his daughter. The patient required repeated blood transfusion. The patient developed profuse bleeding after the transfusion which was given on 23rd September, 02. She was again advised blood transfusion and after the blood transfusion on 25th Sept her condition further worsened for which she was shifted to another hospital and ultimately the patient died on 29 Sept, 02.
- The father (complainant) alleged that the Blood Bank erroneously gave him A+ blood in place of B+ blood and his daughter died because of this wrong blood transfusion. The hospital also did not check the blood and transfused the blood brought by the patient's father and hence he held both the blood bank as well as the doctors of the hospital guilty.
- In defense the treating doctor said he just prescribed blood transfusion but it was actually not transfused in his presence so he claimed innocence. He further argued that had it been mismatched transfusion it was difficult for the patient to survive for 6 days.
- Huma Hospital put forth that they had given a correct requisition slip (mentioning correct blood group) and it was duty of relative to bring correct blood. Hospital argued that the patient was a case of tuberculosis and she died of cardio-respiratory arrest and not due to mismatched blood transfusion.
- The court gave relevance to the fact that complainant has filed a photocopy of the slip for supplying the A+ blood group for the patient Rani—hence Court established that the blood bank did supply wrong blood to the complainant. The Hon'ble Court also did not buy the argument of treating doctor and observed that it was the duty of the consulting surgeon to ensure that the treatment including the blood transfusion was done in accordance to his directions and therefore, if wrong blood transfusion was done he cannot escape from his liability of seeing to it that no such wrong transfusion was done. The court further observed that it is the duty of the blood bank and thereafter, the doctor who has to transfuse the blood that such mistake did not occur. The fact that the Huma Hospital did not submit in the court the copies of transfusion notes after 22nd Sept also went against the hospital.

- The State Forum thus dismissed the appeal of Huma Hospital and the treating doctors.

Mrs Suman vs Government Multi-Speciality Hospital, Chandigarh ... on 1 March, 2012 State Consumer Disputes Redressal Commission:[18]

- Case in brief that Mrs Suman was pregnant admitted in Government Multi-Speciality Hospital for delivery. Since she was anemic, she was advised blood transfusion. It was further stated that soon after the blood was transfused to her, she started feeling uneasy. Complainants allege that the doctors took it casually and informed that everything would be all right. It was further stated that the condition of mother deteriorated, so much so, that it resulted into the death of the full-term fetus, and failure of the kidney of mother. It was further stated that it transpired that the doctors had transfused blood group B+ to Suman, though her blood group was A+.
- The respondents in their defense stated that since it is a Govt Hospital and services provided were free it does not come under purview of Consumer Protection Act (CPA). They mentioned that patient was sixth gravida and had a bad obstetric history (two stillbirths). They denied that intrauterine death (IUD) of baby was due to mismatched transfusion. The hospital did frame a investigative committee which found that the doctors did not check the blood bag and transfused whatever bag was lying with the patient. The lab technician was even suspected of tampering with the sample and records.
- The court observed that the complainant were consumers as they had paid for blood transfusion. The court accepted the inference of investigative committee and concluded that there was negligence per se on the part of the opposite parties. It is a clear case of *res ipsa loquitur* the court observed.
- Hon'ble Court thus allowed the complaint with costs and directed the opposite parties to jointly and severally pay a sum of Rs 4,00,000 as compensation and also pay Rs 50,000 as cost of litigation to the complainant. Opposite party is also directed to bear all the expenses, which may be incurred on the future treatment of complainant No. 1, in any government hospital/health centre/dispensary, etc.

M. Chinnaiyan vs Sri Gokulam Hospital. National Consumer Disputes Redressal. 25 Sept, 06. III (2007) CPJ 228 NC:[19]

- Smt R. Lalitha was advised hysterectomy December 1990. She was transfused two units of blood which was allegedly procured from Queen Mary's Clinical Laboratory. In mid-1994 the patient was diagnosed to have HIV infection. In July 1995, patient developed left-sided hemiparesis, oral candidiasis and pulmonary tuberculosis. CT scan was done which showed that she had glioma of the brain but ultimately she died on 16.8.1995.
- Complainants alleged that neither the Queen Mary's Clinical Laboratory from where the blood was brought, did conduct any test to satisfy itself that it was free from infection like HIV, nor the hospital authorities ensured that the blood which was brought for transfusion to their patient was free from HIV/AIDS.
- The treating doctor in his defense contended that the blood was procured from a Govt approved blood bank and since the blood was certified that it was free from infection of any communicable or contagious diseases, there was no necessity to re-test the blood for same diseases and there was no reason to suspect the

correctness of the certificate. The treating doctor said that during the year 1990s HIV cases were not reported in Salem or for that matter in Tamil Nadu itself and therefore there was no occasion for the first opposite party to have any suspicion of infection of blood with HIV in this case.

- The Queens Mary Lab denied having supplied the blood. They also could not produce any documentary evidence to prove that they were screening blood for HIV infection.
- The court observed that consent of the patient was taken only for hysterectomy and not for blood transfusion. Surgery involves risk and blood transfusion also involves additional risk. Responsibility for the decision to transfuse blood must rest ultimately with the attending physician. Court did not agree with the defense arguments and held both the doctors and blood bank guilty of negligence. Court agreed that the patient developed AIDS due to wrong blood transfusion.
- The Hon'ble court awarded a consolidated sum of Rs 4,00,000 as compensation along with interest of 6% per annum from the date of filing the complaint and this is to be paid jointly and severally by the respondents. The respondents are also directed to pay Rs 10,000 as cost.

Dr Navdeep Singh Khaira vs Sheela Gupta. National Consumer Disputes Redressal. Decided on 7.8.2009:

- Mr Rajkaran (Blood group B Rh –ve) was a patient of chronic renal failure (CRF) and dilated cardiomyopathy (DCM). He was advised to undergo maintenance hemodialysis (HD) regularly. He underwent several sessions of HD. During initial sessions of HD, he was all along transfused with Rh –ve blood, however, on 17.09.1999, he was given Rh +ve blood. He died of cardiac arrest on 19.09.1999. The complainant alleged that the patient died because of mismatched transfusion.
- The treating doctors defence was that (i) Raj Karan was a patient of not only CRF but also DCM, (ii) patients undergoing maintenance HD for CRF have a cardiovascular mortality rate approximately 3 times higher than that of age-matched control subjects, (iii) patients suffering from DCM have a much higher mortality rate than that of the general population, with about 25% dying within 1 year and nearly 50% within 5 years, and (iv) not all Rh –ve persons have anti-Rh (D) antibodies in fact, only a few do so that not all cross-matches of Rh –ve recipients (of blood) from Rh +ve donors or vice versa would be incompatible, as a result of which transfusion of Rh +ve blood may be perfectly safe. In support of these contentions, the opponent party produced extracts of relevant medical texts and published articles in journals. On 17.09.1999, the Blood Bank of OP 2 issued one unit blood of B +ve blood group. This was transfused during the HD session of 17.09.1999, without any complication during the process of HD. In support of their claim, the OPs relied on the medical notes of the process of HD on 17.09.1999, which showed that it went off without any complication. They also referred to the document (cross-matching report of the Blood Bank of OP 2) produced by the complainant herself which is showing that the blood used for transfusion was cross-matched with the blood of the patient but there was no reaction of incompatibility and if the transfused blood had been incompatible, there would have been immediate reaction, in the course of the HD itself hence this is contrary.

- The Hon'ble Commission observed that:
  "According to the last paragraph of the medical text reproduced above, the probability of his developing anti-Rh (D) antibodies, to cause serious complications on account of a single blood transfusion of Rh +ve blood in the course of his HD on 17.09.1999, was low, being immunocompromised already. Moreover, development of anti-Rh (D) antibodies would have taken approximately an average of 120 days after the first transfusion—as against his death on 19.09.1999. Even if the Rh (D) antibodies developed extremely rapidly in Raj Karan, these antibodies could have caused fatal reaction, when he received a second transfusion of Rh (D) +ve blood. The hemodialysis record on 17.09.1999 did not show any adverse reaction on that date."
- The Commission sided with the defence arguments and set aside the judgment of State Commission implicating the treating nephrologist and hospital.

In Mississippi Baptist Hospital vs Holmes, the hospital technician mixed up the decedent's blood sample with the blood sample of another patient on the same floor. Thereupon, he accurately typed both samples but mislabeled each sample as result of his original error:[20]

- As a result, the decedent, while undergoing surgery, was transfused incompatible blood and died.
- The Supreme Court of Mississippi, overrule the state's charitable immunity doctrine and held the hospital liable for damages due to the negligence of its technician.

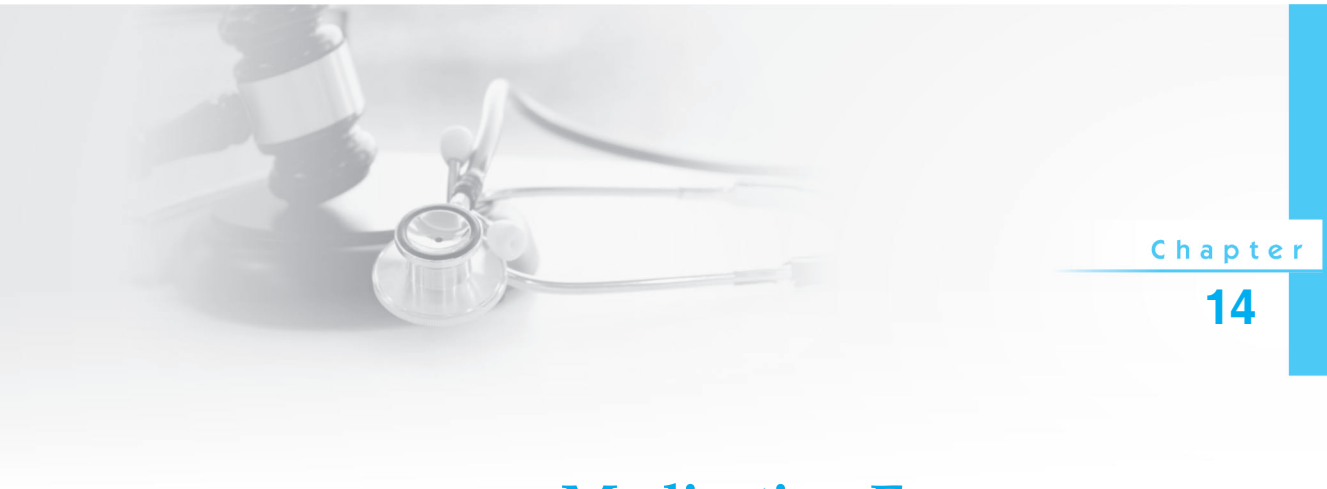
CONCLUSION

Medicolegal adverse effects on the medical fraternity can be minimized by following all the recommendations. All necessary steps taken (with proper documentation) in case of adverse reaction will help in saving the reputation of the medical professionals.[21] Blood transfusion is a well-accepted procedure in modern day clinical practice and no one should be afraid of stray cases of litigation due to adverse event and reactions of blood transfusion. The need of the hour is to be well cautious with the law and follow the ethics of blood transfusion.

REFERENCES

1. Agarwal N. Blood Products/Substitutes. Available at https://www.slideshare.net/itscooldude/blood-products-and-substitutes-nikhil?qid=aeee7365-b14c-4670-ac61-6401177a7bcb&v=&b=&from_search=5. Accessed on 1.9.2020.
2. Standards for Blood Banks and Blood Transfusion Services. NACO Ministry of Health & Family welfare, Govt of India, New Delhi. 2007, 33.
3. Saran RK. Transfusion Medicine Technical Manual, DGHS Ministry of Health & Family welfare, Govt of India, New Delhi. 2nd Ed., 2003.
4. Aubron C, Aries P, Le Niger C, Sparrow RL, Ozier Y. How clinicians can minimize transfusion-related adverse events? *Transfus Clin Biol* 2018 Nov;25(4):257–61.
5. Jasinski S, Glasser CL. Catastrophic Delayed Hemolytic Transfusion Reaction in a Patient With Sickle Cell Disease Without Alloantibodies: Case Report and Review of Literature. *J. Pediatr. Hematol. Oncol* 2019 Nov;41(8):624–26.
6. Erony SM, Marshall CE, Gehrie EA. The epidemiology of bacterial culture-positive and septic transfusion reactions at a large tertiary academic center: 2009 to 2016. *Transfusion* 2018 Aug;58(8):1933–39.

7. Toy P, Lowell C. Definition, mechanisms, incidence and clinical relevance available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2767181/. Accessed on 28.08.2020.
8. Silvergleid AJ, Kleinman S, Tirnauer JS. Transfusion-associated graft-versus-host disease. Available at https://www.uptodate.com/contents/transfusion-associated-graft-versus-host-disease. Accessed on 31.8.2020.
9. Agnihotri N, Agnihotri A. Transfusion associated circulatory overload. *Indian J Crit Care Med* 2014; 18(6): 396–98.
10. Kai Li, Yuan Xu. Citrate metabolism in blood transfusions and its relationship due to metabolic alkalosis and respiratory acidosis. *Int J Clin Exp Med* 2015; 8(4): 6578–84.
11. Smith BR, Aguero RM, Anastasi J. Academy of Clinical Laboratory Physicians and Scientists. Educating medical students in laboratory medicine: a proposed curriculum. *Am J Clin Pathol* 2010; 133(4):533–42.
12. Banacloch JG. Granulocyte Transfusions: A Concise Review for Practitioners. *Cytotherapy* 2017; 19(11): 1256–69. Available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5716890. Accessed on 30.8.2020.
13. Ekiaby ME, Shabrawishi BTC. Platelet transfusion. Available at https://www.slideshare.net/egyfellow/platelet-transfusion. Accessed on 25.8.2020.
14. Shamim A. Platelet transfusion. Available at https://www.slideshare.net/zahoor061/platelet-transfusion-afshan on 20.8.2020.
15. Fresh Frozen Plasma. Available at https://www.slideshare.net/PraveenNagula/fresh-frozen-plasma?from_action=save. Assessed on 15.8.2020.
16. Elhence P.. Ethical issues in transfusion medicine. Indian J Med Ethics.2006;3(3). Available at http://www.issuesinmedicalethics.org/143oa87.html. Accessed on 25.8.2020.
17. Huma Hospital vs Saleem Ansari on 13 September, 2017. Available at https://indian-kanoon.org/doc/26408922/. Accessed on 22.8.2020.
18. M. Chinnaiyan vs Sri Gokulam Hospital and Anr. on 25 September, 2006. Available at https://indiankanoon.org/doc/1919829/. Accessed on 23.8.2020.
19. Dr. Navdeep Singh Khaira vs Sheela Gupta on 7 August, 2009. Available at https://indiankanoon.org/doc/122213115/ Accessed on 22.8.2020.
20. Thomas JA. Blood Transfusion Liability available at https://engagedscholarship.csuohio.edu/clevstlrev/vol10/iss3/11. Accessed on 18.08.2020.
21. Gorea RK Medicolegal aspects of blood transfusion J Punjab Acad Forensic Med Toxicol 2010 Available at https://www.researchgate.net/publication/236624886. Accessed on 22.08.2020.



Chapter
14

Medication Errors

Sheikh Minhaj Ahmed, Neil W Castellino

According to the National Coordinating Council for Medication Error Reporting and Prevention, a **medication error** is defined as "any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient or consumer." [Department of Health (DH), 2004.] This would include, for example, taking a medication at the wrong time, at the wrong dosage, or inadvertently with another medication that creates a harmful side effect.

Medical error can also be defined as ''the failure of a planned action to be completed as intended or the use of a wrong plan to achieve an aim'', often is either intercepted by redundancies in the system before it makes it to patients or frequently is not clinically significant.

For example, providing a dose of acetaminophen 1 hour late technically is a medication error, yet this error is unlikely to translate into patient harm. **Adverse effects** (AEs), however, defined as ''injuries, large or small, caused by medical management rather than the underlying condition of the patient'' are, by definition, linked to harm and, thus, the ultimate outcome that patient safety interventions aim to decrease. It is critical to understand that AEs not always are the result of error such as in the case where a patient has anaphylaxis for the first time after administration of an appropriate dose of penicillin. Medical error and adverse medical events are not synonymous and, therefore, require different intervention strategies to impact their rates (Fig. 14.1).

Reasons for the Vulnerability of Medication Errors in Children

- Pharmacological factors such as age-based variability in absorption.
- Metabolism and excretion of drugs.
- Risk of overdosing.
- The need for dose calculations based on constant changes of weight and surface area.
- The need for frequent unit conversion to reflect.
- The very small dose required.

Magnitude of Problem

From the Literature

- Bates et al reported that, MEs prolong hospital stays by 2 days and increase the costs by $2,000–2,500 per patient.

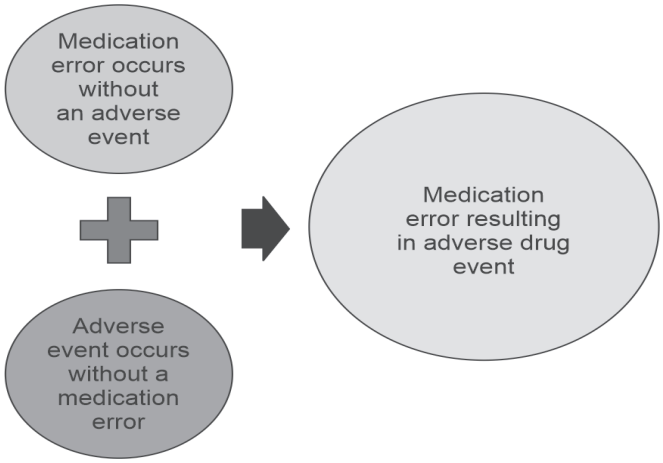

Medication error occurs without an adverse event
Adverse event occurs without a medication error
Medication error resulting in adverse drug event

Fig. 14.1: Medication error and adverse events

- Vazin et al reported 37.6% of administration, 21.1% prescription and 10.0% transcription errors in Shiraz University of Medical Sciences, Iran.
- Rothschild et al observed 0.078 errors per patient, and 0.029 errors per medication. Highest rate of errors pertained to dosing errors, drug omission, and wrong frequency errors.

Organisational Factors

The 'Swiss cheese model' (Reason, 1997) of system failure can help us understand how medication errors can occur (Fig. 14.2).

Each slice of cheese represents a safeguard against error; whilst each 'slice', or safeguard, should be intact, in reality the slices are full of holes. As the number of safeguards increases, it becomes less likely that the 'holes' in the system will align sufficiently to allow an error to occur.

There are two reasons for holes opening up in the layers of defence: **Active failures and latent conditions** (Reason, 1990).

Active failures result from unsafe practices of the people working with a system, for example the doctor failing to check for drug allergies or the pharmacist failing to identify an incorrect dose on a prescription.

Latent conditions are the aspects of the systems, such as the resources available and medication policies, which, either alone or in combination with an active failure, can result in error. Examples of latent conditions include:

- The lack of a computerised prescribing system with in-built systems to highlight an erroneous prescription;
- The absence of an effective communication system between primary and secondary care;
- The absence of system checks to ensure that drugs with similar names or packaging are not wrongly administered.

CLASSIFICATION OF MEDICATION ERRORS

Can be classified in various ways.

- Some medication error reporting system focus on type of error, e.g. dispensing, administering, or prescribing errors.

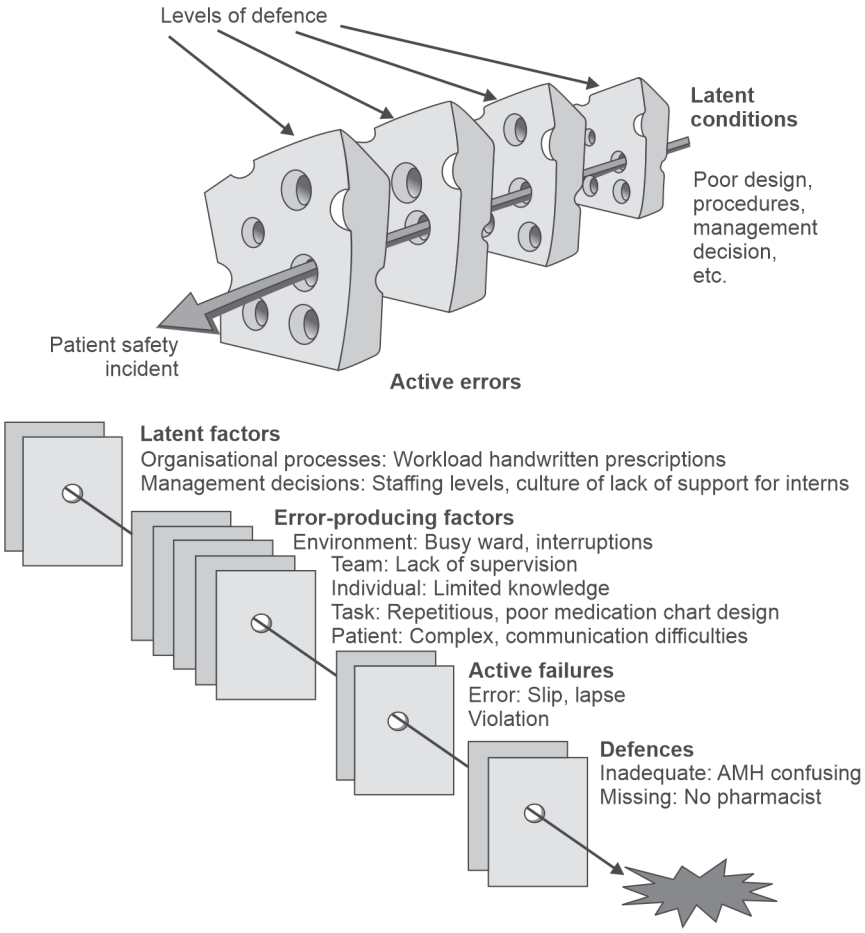


Fig. 14.2: Reason's Swiss cheese model

- Other system may be more interested in the outcome of the errors. It focuses on what effect, if any, the error had on patient.
- Error may be classified on the profession committing the error or the particular drug involved in the error; which is mentioned below.

Types of ME

- *Omission*: Failure to administer prescribed dose excluding patient refusals.
- *Unauthorized drug*: Wrong patient, duplicate dose, wrong drug. Incorrect drugs and IV fluids are given because of similar names and packing. An example of wrong drug could be mixing up of injection amikacin with injection wymesone as both the vials may be of same color and size. Further still if injection heparin stock solution of 1:1 concentration prepared in a normal saline bottle, then mixing up with a plain normal saline kept near by.
- *Wrong dose*: Dose 10% higher or lower than prescribed. The drug can be administered rightly if smaller syringe, e.g. 1 cc of 40 divisions is used and dose calculated appropriately. Commonly nurses (especially those new to the unit) calculate smaller dose in this fashion—injection netilmycin 1 ml = 200 mg = 40 units,

hence 20 units = 100 mg, 10 units = 50 mg and 5 units = 25 mg ..... Rather than calculating directly that if 1 ml = 200 mg then 0.1 ml = 20 mg = 4 units in an insulin syringe.

- *Wrong route*: Administration through routes other than prescribed including wrong site (e.g. left eye instead of right eye).
- *Wrong rate*: Other than prescribed rate. In infusions are being administered through a pediatric drip set then it is easier to use the following formula to calculate the drip rate.
- Amount to be infused X drop factor [60 for a pediatric drip], total time in 15 minutes for an IV set.
- *Wrong farm*, e.g. ointment instead of a solution.
- *Wrong time*: 30 min or more outside the prescribed time.
- *Wrong preparation technique*: Incorrect preparation of a dose, e.g. incorrect dilution, using an expired drug, not shaking a suspension, mixing incompatible drugs.
- Incorrect administration technique, e.g. fluids given by an extravasated IV line, arterial instead of venous, not using a Z-track technique for IM injection, etc.
- Dissolved solution and stock solution of certain drugs are not be used after first use, e.g injection amoxiclav, therefore inadvertent subsequent use of them may lead to ineffective therapy.
- *Deteriorated drug error*: That have expired or deteriorated prematurely due to improper storage conditions.

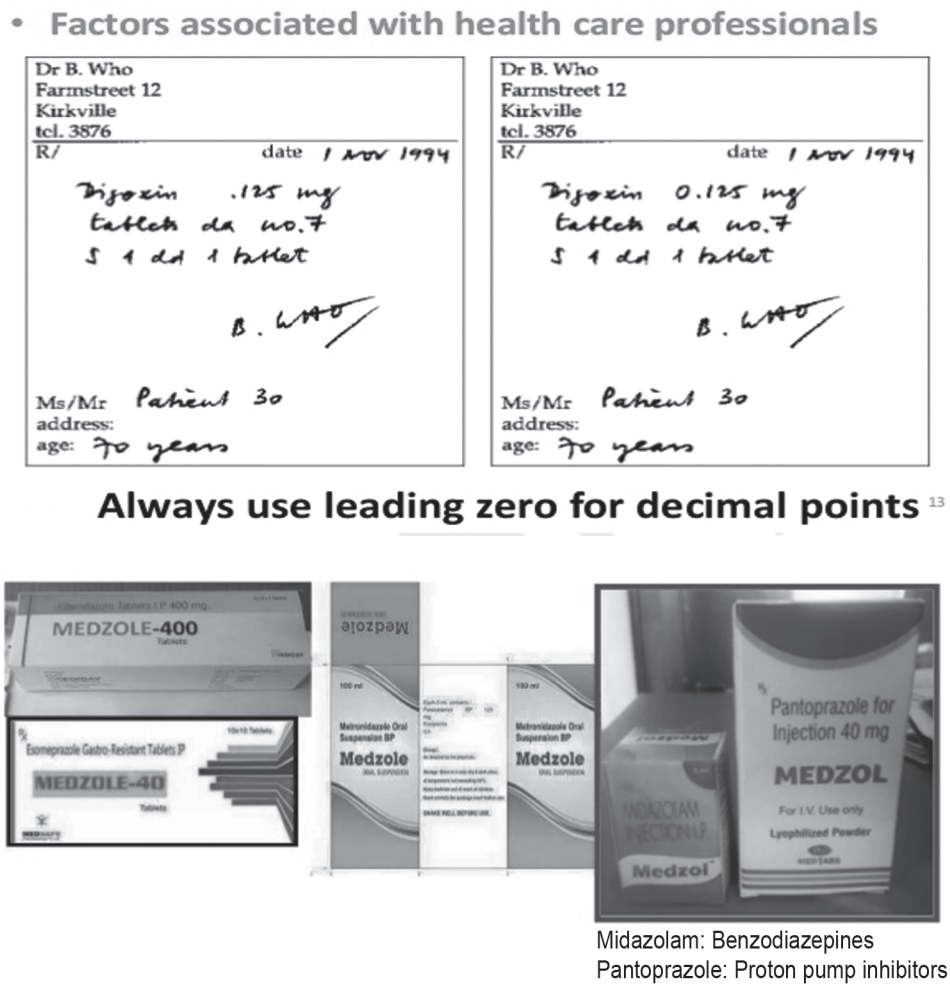
The National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) an organization composed of 19 individual organizations and individual members, including the FDA, American Medical Association, American Pharmacist Association, United States Pharmacopoeia and several other has developed a detail definition of what constitute medication error. Similarly, NCC MERP has proposed a medication error index that serves to categorized error based on the severity or outcome of the error; which is divided into 4 main categories and 9 subcategories (Table 14.1).

Table 14.1: Medication error index (NCC MERP)

1. No error	Category A	Circumstances or events that have the capacity of cause error
2. Error, no harm	Category B	An error occurred but the medication did not reach the patient
	Category C	An error occurred that reached the patient but did not cause the patient harm
	Category D	An error occurred that resulted in the need for increased patient monitoring, but caused no patient harm
3. Error, harm	Category E	Error occurred that resulted in the need for treatment or intervention and caused temporary patient harm
	Category F	Error occurred that resulted in initial or prolonged hospitalization and caused temporary patient harm
	Category G	Error occurred that resulted a permanent patient harm
	Category H	Error occurred that resulted in near death event (anaphylaxis and cardiac arrest)
4. Error, death	Category I	An error occurred resulting in patient death

Causes of Medication Errors (Fig. 14.3)

- Factors associated with health care professionals (doctors)
  - Prescription: Prescription errors, including illegible handwriting, irrational, inappropriate, and ineffective prescribing
  - Dispensing the formulation: Wrong drug, wrong formulation, wrong label.
- Factors associated with health care professionals (nurses)
  - Inadequate drug knowledge and experience
  - Inadequate knowledge of the patient
  - Inadequate perception of risk
  - Lack of therapeutic training
  - Overworked or fatigued health care professionals
  - Physical and emotional health issues
  - Poor communication between health care professional and with patients
- Factors associated with patients
  - Patient characteristics



Midazolam: Benzodiazepines
Pantoprazole: Proton pump inhibitors

Fig. 14.3: Causes of medication errors

  - Complexity of clinical case, including multiple health conditions, polypharmacy and high-risk medications
  - Taking the drug: Wrong dose, wrong route, wrong frequency, wrong duration
- Other factors:
  - The work environment
  - Medicines
  - Tasks
  - Computerized information systems
  - Primary–secondary care interface

Prevention of ME

- Prescribers: Physician's prescriptions and drug order are means of communicating, so they must be legible, clear, and unambiguous. The following steps may help to ensure that medication orders communicate safely and effectively.
  a. Confirm that the patient's weight is correct for weight-based dosages.
  b. Write out instructions rather than using abbreviations. BT bedtime mistaken as 'BID' use 'bedtime' IN intranasal mistaken as 'IM' or 'IV' use 'intranasal' or 'NAS'.
  c. Avoid vague instructions (e.g. take as directed; no order should be written without dose and volume where appropriate)
  d. Specify exact dosage strength.
  e. Avoid use of a terminal zero to the right of the decimal point (e.g. use 5 rather than 5.0) to minimize 10-fold dosing errors.
  f. Use a zero to the left of a dose less than 1 (e.g. use 0.1 rather than .1) to avoid 10-fold dosing errors.
  g. Avoid abbreviations of drug names (e.g. MS may mean morphine sulfate or magnesium sulphate)
  h. Spell out dosage units rather than using abbreviations (e.g. milligram or microgram rather than mg or μg; units rather than U).
  i. Ensure that prescriptions and signatures are legible, even if it means printing the prescriber's name that corresponds to the signature.
  j. Avoid verbal orders except in emergencies
     - Sound alike medications
     - Clotrimazole: Co-trimoxazole
     - Oxycontin: Oxynorm (oxycodone)
     - Dopamine: Dobutamine
     - Adrenaline: Atropine
     - Noradrenaline: Adrenaline
- Pharmacists:
  a. Monitor the medication safety literature
  b. Follow a medication error (avoidance plan)
  c. Verify the accurate entry of data on new prescriptions (avoid abbreviations; use tall man lettering)
  d. Report errors

- Nurses
  a. Be familiar with medication ordering and use system.
  b. Verify drug orders before medication administration.
  c. Check medication calculations with a second individual.
  d. Unusually large volumes or dosages units for a single patient dose should be verified.
  e. Remain familiar with the operation of medication administration devices and the potential for errors with such devices.
  f. Implementing medication reviews and reconciliation: **Medication reconciliation** is the process of creating the most accurate list possible of all medications a patient is taking—including drug name, dosage, frequency, and route—and comparing that list against the physician's admission, transfer, and/or discharge orders, with the goal of providing correct medications to the patient at all transition points within the hospital.
  g. Participate/lead in evaluations of the efficacy of new safety systems and technology—support a culture that values accurate reporting of medication errors.
  h. Always be conscious of the 5 rights of medication administration.
  i. Confirm patient identity before administration of each dose.
     – Right patient
     – Right drug
     – Right dose
     – Right route
     – Right time

Electronic Prescription

One strategy to minimise medication errors is the use of electronic systems for prescribing, dispensing and administering medications. Electronic systems can reduce errors, although the evidence demonstrates variable success—one drawback is the reduced opportunities for face-to-face discussion about patient medication between nurses, doctors, pharmacist and the patient.

Guidelines for Prescription Writing

- Prescriptions should be written indelibly.
- Prescriptions should be dated, stating the full name and address of the patient.
- Prescriptions should be signed by the prescriber.
- The age and date of birth of the patient should preferably be stated.
- The unnecessary use of decimal points should be avoided.
- Quantities of 1 g or more should be written as 1 g, etc.
- Quantities less than 1 g should be written in milligrams (mg).
- Quantities less than 1 mg should be written in micrograms.
- If decimals are used, a zero should be written in front of the decimal point.
- Micrograms and nanograms should not be abbreviated.
- Dose and dose frequency should be stated; for 'as required 'medicines a minimum dose interval should be specified.

- Drug names should not be abbreviated.
- Specific directions should be written in English, with the exception of some Latin abbreviation (as listed in the British National Formulary).

Common Route Abbreviations for Prescription Writing

- PO (by mouth)
- PR (per rectum)
- IM (intramuscular)
- IV (intravenous)
- ID (intradermal)
- IN (intranasal)
- TP (topical)
- SL (sublingual)
- BUCC (buccal)
- IP (intraperitoneal)

Do not use List

- U or u (unit), use 'unit'
- IU (international unit), use 'International Unit'
- Q.D./QD/q.d./qd, use 'daily'
- Q.O.D./QOD/q.o.d./qod, use 'every other day'
- Trailing zeros (#.0 mg), use # mg
- Lack of leading zero (.#), use 0.# mg
- MS, use 'morphine sulfate' or 'magnesium sulfate'
- MSO_4 and $MgSO_4$, use 'morphine sulfate' or 'magnesium sulfate.'

Common Frequencies Abbreviations for Prescription Writing

- Daily (no abbreviation)
- Every other day (no abbreviation)
- BID/b.i.d. (twice a day)
- TID/t.i.d. (three times a day)
- QID/q.i.d (four times a day)
- QHS (every bedtime)
- Q4h (every 4 hours)
- Q4–6h (every 4 to 6 hours)
- QWK (every week)

Chapter
15

Mistakes by Staff

Rajakumar Marol

Health care workers are not demigods, but are human beings and like other human beings, make mistakes. These are the mistakes by health care providers like physicians, surgeons, anesthetists, nurses, technicians and physiotherapists, etc. who are employed by the hospital. It does not matter whether they are permanent or temporary, full time or part time. It also applies to the negligence of the hospital administration itself.

Mistakes by hospital staff is quite common. Medical errors are the third leading cause of death after heart disease and cancer. John Hopkins study claims that more than 25000 people in US die every year from medical errors and some reports claim even more, as high as 440000.

Various Types of Mistakes Made by Hospital Staff

1. Poor coordination with next phase of care (poor communication)
   a. Nursing shift charges to other nursing staff
   b. Nursing staff to physicians
   c. ICU to lower level of care
   d. Specialist to continued care system
   e. Facility to facility
2. Laboratory errors: Most errors are preanalytic and involve problems with specimens that are hemolysed, improperly collected (collected in insufficient quantity), not labeled and contamination, etc. These errors are not associated with harm, but there is potential for significant injury.
3. Test results reporting error: Failure to order an appropriate test, error while conducting the test, incorrect interpretation of test, or failure to follow-up the report can have direct consequences for the patient. It can result in delayed treatment, wrong treatment or no treatment at all.
4. Retained foreign object during surgery.
5. Patients fall due to nonavailability of staff during the time of patients' nature calls, postoperative periods or unconscious patient.
6. Violence in hospitals because of failure to adequately manage behavior of patients and attenders in acute crisis.
7. Improper documentation to:
   – Record health and drug information
   – Record drugs given

- Record any discontinued medication
- Record nursing actions
- Record the changes in the condition of patient
- Record orders given by doctors for the patient care.

8. Infections: Not adhering to hospital infections control guidelines (according to CDC hospital infections account for 99000 deaths in USA alone).
9. Medication errors:
   - Administering worng medication
   - Dispensing an incorrect dosage
   - Giving a prescription to the wrong patient
   - Giving medication without testing for allergy
   - Mixing with wrong diluents
10. Inadequate follow-up after treatment/procedure
11. Inappropriate handling of system error/technical failure

Causes of Mistakes by Health Care Professionals

1. Under staffing of nurses than required
2. Overwork stress or fatigue of health care staff
3. Failure of communication or working together as a team
4. Complexity of medical care
5. Poor training of health care professionals
6. Poor supervision of health care professionals
7. Uncaring heath care staff
8. Poor hand writing or follow-up of doctors instructions
9. Inadequate support systems
10. Look-alike and sound-alike drugs
11. High volume of patients
12. Patients with same names and similar ages
13. Overconfidence and too much reliance on memory
14. Lack of computer knowledge
15. Patients themselves
16. Parents or caretaker related

VICARIOUS LIABILITY

It is an indirect responsibility, i.e. the responsibility of A for the wrongful acts of B against C. This doctrine is held in cases where hospital is held responsible for the negligent acts of its employee like employed doctors including resident doctors, nurses, locum, its partners and other staff in the process of treating the patients.

In Rekha Gupta vs Bombay Hospital Trust, II (2003) CPJ 160(NC), the concept of vicarious liability was explained by the State Forum under Sections 2(1)(d) and 2 (1) (0) of Consumer Protection Act, 1986.

Respondent Superior

Respondent superior means let master be answerable. This is based on the doctrine that it is the master who is deriving the benefits (financial or otherwise) from the

actions of B and is responsible for providing facilities and environment for proper functioning and also for selecting the right person for the job.

Employer is considered as a hiring and firing authority. Therefore, it is not necessarily the owner of organization who will be considered as vicariously liable, it is also the individuals in the senior management positions who can be held vicariously liable for the acts of its employees. Doctors in India can be held liable for their services individually or vicariously.

A general practitioner often employ a locum to look after their clinics in case of their absence. However, he has to ensure that a suitable qualified person is appointed; failure to do so may result in direct liability instead of vicarious liability.

Polyclinic means a place where doctors of different specialities practice with common staff and other facilities. Since every doctor is practicing individually, he would be responsible for his own negligence and not for others. A doctor working in a multispeciality hospital may also be vicariously liable if the negligence occurs during the care of his patient in addition to the hospital's liability for the negligence of its staff. Other doctors may get involved as partners of the polyclinic depending upon the agreement.

Corporate liability is based on the doctrine that the supervisory responsibility to ensure that the patients are examined and treated well in its premises and adequate facilities for such treatment is provided by the hospital. The hospital may be directly held responsible for faulty premises, equipment, inadequate/unqualified staff, in addition to the fault of their employees.

Court Judgments on Vicarious Liability

1. **Vicarious liability for nonavailability of hospital staff to assist patient: Mr M Ramesh Reddy vs State of Andhra Pradesh [2003(1) CLD 81 (AP SCDRC)]:** Here an obstetric patient had fallen in bathroom and died, Hon'ble court held hospital authorities responsible for keeping slippery bathrooms with huge fungal infection.
2. **Vicarious liability for not providing clean environment: Joseph Alias Pappachan and others vs Dr George Moonjely and another [1994(1)KLJ 782(Ker-HC)]:** A lady died after postpartum sterilization operation and was found to have intestinal perforation and fecal peritonitis, which was documented at another hospital where she was referred afterwards. Court concluded that hospital management is vicariously liable for not providing adequate facilities for clean environment for surgery. The court observed that persons who run a hospital are in law under the self; whenever they accept a patient for treatment, they must use reasonable care and skill to cure him of his ailment.
3. **Vicarious liability of hospital for the negligence of nursing staff : A M Mathew vs Director Karuna hospital and others [1998(1)CPJ 476: 1998(1)CPR39 (Ker. SCDRC)]:** The complainant's minor son aged 8½ years was taken to Karuna Hospital for fever and tonsillitis. On advice of the doctor, the staff nurse gave injection paracetamol in the left buttocks, following which the boy developed left foot drop. He was referred to a neurologist who diagnosed the condition as left sciatic never palsy, and the left leg disabled. The condition occurred due to the injection needle entering into the sciatic nerve due to negligence of the nurse.

The hospital contended that this was an accepted complication and, if the injection had caused any injury to the sciatic never, it was accidental. However, the staff nurse had left employment soon after the lawyer's notice and could not be contacted. Also she was not qualified to administer the injection. This amounted to actionable negligence.Vacarious liability of hospital proved and a compensation of Rs 1,05,000 awarded against the hospital with additional cost of Rs 1,000.

4. **Vicarious liability of hospital for consultant doctors [Rekha Gupta vs Bombay Hospital Trust and another, 2003 (2) CPJ 160 (NCDRC)]:** Hospital employing staff and deducting 20% commission payable to consultants cannot escape liability for medical negligence of consultants: Complaint against hospital maintainable under Sections 2(1) (d) and 2(1) (o) of Consumer Protection Act, 1986.
5. **Vicarious liability: Negligence of visiting doctor—Tort [Aparna Dutta vs Apollo Hospitals Enterprise Ltd, 2002 ACJ 954 (Mad-HC)]:** Compensation for medical negligence of doctor in conducting surgery leaving a foreign object inside the body of patient. Plea of hospital-disowning liability on the ground that the doctor was an independent consultant and not an employee of the hospital. Unsustainable: Patient admitted in the hospital after collecting fees and it was the hospital that arranged the services of the doctor. Hospital, therefore, vicariously liable for negligence of doctor despite absence of master–servant relationship between the hospital and the doctor.
6. **Vicarious liability: Obstetrics/Gynecology [Aleyamma Varghese vs Dewan Bahadur Dr V. Varghese and others, 1997 (3) CPJ 165 (Ker. SCDRC):** Sponge left behind by the negligence of nurse.Vicarious liability of hospital: A compensation of Rs 98,000 was awarded against the hospital and insurance company.
7. **Vicarious liability: Non-availability of doctor/anesthetist—delivery case in a government hospital—negligence—tort—vicarious liability of state [Leela Bai vs Sebastian and others, 2002 (2) CPJ 363 (Ker. HC) (DB)]:** Excessive bleeding after giving birth to a child and emergency surgery required could not be performed in time due to nonavailability of doctor/anesthetist resulting in death of patient—state government is vicariously liable for Rs 137500 compensation awarded by the court.
8. **Vicarious liability: Pediatrics [Master P.M. Aswin and others vs Manipal Hospital, Bengaluru, 1997 (1) CPJ 238: 1997 (1) Cpr 393 (Karn. SCDRC)]:** Burn injuries: Both legs of child were burnt by keeping extremely hot water bags during surgery. Negligence held: Vicarious liability of hospital—anesthetist also made liable—compensation of Rs 5 lakh awarded.
9. **Vicarious liability of senior doctor for the mistake of junior staff: Wilsher vs Essex area health authority [1986 3 AIIER 801(CA)]:** A premature infant was put on oxygen and arterial oxygen was monitored by the catheter inserted by the junior doctor. However, the catheter was in vein which was not recognized by the senior doctor inspite of consulting him, thus continuing oxygen supplementation. So, the plaintiff lost his sight and the senior doctor was vicariously held responsible.
10. **Vicarious liability of state government: Shakuntala Sharma vs State of U.P. [2001, ACJ 620 (AII.-HC) (DB)]:** Vasectomy sterilisation failure by government doctor, compensation to be given by state government on basis of vicarious liability for negligence of its servant.

11. **Vicarious liability of state government: State of Haryana and others vs Smt Santra [2000 (1) CPJ53 (SC)]:** Failure of operation under family planning scheme and subsequent conception—compensation to be given by state government on basis of vicarious liability for negligence of its servant.
12. **Vicarious liability of Union of India Smt A V Janaki Amma vs Union of India [2004 (7) CLD 662 (AP-HC)]:** Death of the wife of an army personnel due to negligence of doctors in military hospital.
13. **Wrong injection by nurse not supervised by resident doctor: Springs Meadows Hospital vs Harjot Ahluwalia, [1998 (3) CPJ 1: JT 1998 (2) SC 620 (SC), CPR 1 (SC)]:** Injection cloroquine was given by unqualified nurse resulting in brain damage of the child. An award of Rs 12.5 lakh as a compensation to the child and Rs 5 lakh as a compensation to the parents was ordered.
14. **Vicarious liability of government hospital—Kalavati vs State of Himachal Pradesh [1988 ACJ 780 HP-HC]:** Wrong gas was administered by anesthetist and the government was held responsible.

PREVENTION

A review of 1133 medical records of hospital errors showed that 70% are preventable and 30% are not preventable. A study based on the review of 15000 medical records in Colorado and Utah in USA found that 54% of surgical errors were preventable. Mistakes by staff can be prevented by taking following measures:

1. Create a health care culture of safety
2. Proper communication at all levels
3. Issuing all prescriptions electronically
4. Following safe prescription practices
5. Avoiding polypharmacy
6. Monitoring drugs effectively
7. Efficient follow-up on tests and referrals
8. Inclusion of pharmacists during hospital rounds
9. Apology whenever necessary and no punishment
10. Encouraging reporting of mistakes by staff
11. Involving patients in their health care and educating them about their medical care
12. Work to reduce infections especially by following best practices for hand hygiene
13. Create awareness among health professionals by including it in their curriculum
14. System improvement through efforts at the level of all the stakeholders
15. Employ only trained professionals including nursing staff and technicians
16. Train the staff regularly through CMEs or workshops about recent advances
17. Retaining the old and already trained staff
18. Through documented standard operating procedures (SOP) and monitor adherence to clinical protocols
19. Implementation of staff training on basic violence prevention techniques
20. Documentation of all the mistakes done by staff.

BIBLIOGRAPHY

1. Dr Jagadeesh Singh Viswabhushan. Medical negligence and compensation 2007. Bharat Publications 13.72 b Vicarious Liability, p. 616–18.
2. James B. Lieber. How to make hospitals less deadly? Wall street journal, May 17, 2016.
3. Lichtenstein, et al. Laboratory errors in pediatric emergency department network. An analysis of incident reports. Pediatric Emergency Care. 2016 Oct: 32 (10): 653–57.
4. Malcolm Khan, et al. Clinical Negligence, 2nd edn, 2002; p. 86.
5. Medical Negligence. The role of America's civil justice system in protecting patient rights, February 2011.
6. Shashi Mohan Sardana. Errors in medical practice. In: Tiwari Satish, Baldwa Mahesh, Tiwari Mukul, Kuthe Alka. Textbook on Medicolegal Issues related to Various Medical Specialities, 2nd edition, p. 78–101.

Chapter
16

Equipment Failure and Faulty Medical Devices

Pankaj Agrawal

INTRODUCTION

Medical equipment or devices are developed to assist medical professionals in treating patients. They help in diagnosing, prevention and treatment of numerous illnesses and injuries. They play a crucial role for efficient health delivery in any country and quality of health services can be effectively improved by the availability and optimal utilization of medical equipment. They range from simple tongue depressors to asthmatic inhalers, from safety critical pacemakers to large and complex MRI scanners.

Complex medical pieces of equipment play an important role in the care of critically ill patients and these medical pieces of equipment have the potential to develop fault, to fail or to be used incorrectly. That may be an important cause of actual or potential harm to a patient under critical care. The increasing number of medicolegal cases may be potentially contributed by the failure of medical equipment.

Definition of Medical Device/Equipment[1]

The Medical Device (Amendment) Rules, 2020 (MDR Amendment) were notified by Indian Government on February 11, 2020 to include all medical devices as "drug" under the DCA and MDR. A new definition of medical device was notified by these rules:

All devices including an instrument, apparatus, appliance, implant, material or other article, whether used alone or in combination, including a software or an accessory, intended by its manufacturer to be used specially for human beings or animals which does not achieve the primary intended action in or on human body or animals by any pharmacological or immunological or metabolic means, but which may assist in its intended function by such means for one or more of the specific purposes of:

i. *diagnosis, prevention, monitoring, treatment or alleviation of any disease or disorder;*
ii. *diagnosis, monitoring, treatment, alleviation or assistance for, any injury or disability;*
iii. *investigation, replacement or modification or support of the anatomy or of a physiological process;*
iv. *supporting or sustaining life;*
v. *disinfection of medical devices; and*
vi. *Control of conception.*

Factors Causing Equipment Failure

The smooth operation of any medical equipment depends on the interactions between the device (device itself and its accessories), the clinician/carer (doctors, nurses, and allied health care professionals), and the patient.[2] This interaction is also influenced by the surrounding environment in the form of physical and supporting infrastructures that include a physical building, electrical power supplies, physical mounting and position of the devices. The supporting system is equally important because it ensures the availability of the equipment and its consumables and accessories, maintenance arrangements and training support for users for safe, reliable and effective operation of medical equipment. Interactions between these all elements and its effects on medical equipment have been summarised in Fig. 16.1.

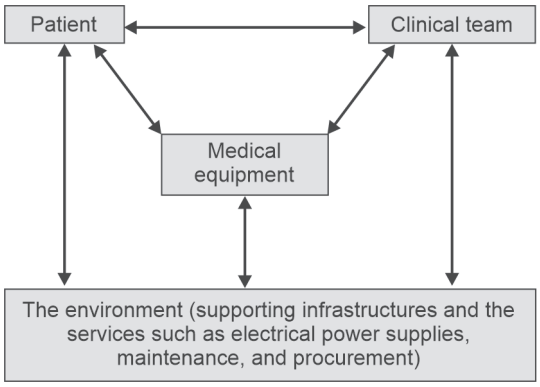

Patient
Clinical team
Medical equipment
The environment (supporting infrastructures and the services such as electrical power supplies, maintenance, and procurement)

Fig. 16.1: Interaction of different factors including clinical team, patients, surrounding environment and medical equipment[2]

Any derangement in the interaction between medical equipment, clinical team using it, patient and surrounding environment including the organization may lead to equipment failure. Faulty medical equipment especially in critical care settings may lead to potential harm to patient's health resulting in medicolegal implications. So, it is imperative to know the cause of equipment or device failure to fix the liability. Causes of faulty medical devices and equipment can be categorised as follows.

Manufacturer Related Errors

Manufacturer related error can further categorised into two types:

Equipment/device design errors: Poor design can be an important cause of device failure specially used in complex clinical conditions that can lead to adverse event even in presence of highly trained operator. Poor ergonomic design may result in poor usability leading to instances of device failure. Devices must be designed in user-friendly manner, it should match the way clinicians think and operate them in their usual working conditions.[3]

Other than ergonomic failures are technical design failures. Other causes of manufacturing related device failures include random component or subassembly failure, battery failure, wear and tear, and chemical damage. The consumables and accessories used with medical devices are equally important since the faulty consumables and accessories can lead to adverse events.

Manufacturing errors: When the equipment specification or details have not been implemented according to the standard process, manufacturing errors may occur. Failure to manufacture the device within the required dimensional tolerances and inappropriate equipment sterilisation practices are the example of such errors.

User/Operator Related Errors

Operator is responsible for the proper process of deployment of equipment that includes selection of the appropriate device, setting it up (including attaching accessories and consumables), setting the controls and alarms, performing pre-use checks, and ensuring safe and effective performance during its operation. Before using any device, operator/clinical team should receive the proper competency training and develop the understanding about the equipment recommended by the manufacturer of the device.[2] So, any equipment failure resulting from deviation from approved operating procedures and instructions for use would be ascribed to the error of operator.

Distraction and fatigue in often busy clinical environment is also included under operator error. Although rare but deliberate or malicious misuse by operator must be incorporated as a cause of adverse incident. Sometimes device use error may be the direct consequence of poor interaction and interpretation of equipment by the user due to suboptimal design of equipment.[4]

Error at Infrastructure/Environment or Organization

In a broader way, infrastructure includes the hospital or organisation where health care and equipment is placed. It also includes the maintenance support system and background infrastructure. It is the responsibility of the organization to provide the safe and effective medical devices at the point of need. Many factors are responsible for lack of availability including lack of procurement, failures of resource management, housekeeping, and delayed maintenance. Deficiency in basic requirements such as failure in supply of electricity or medical gases or electromagnetic interference by mobile, are included in infrastructure problems.

Some adverse incidents can be attributed to the poor device layout associated with difficulties in accessing controls or seeing displays. Faulty maintenance, poor installation and commissioning may also contribute to adverse incidents.

Error Related with Patient

Some of the incidents may be attributed to the patient himself or his visitors. The interaction between patient's condition and medical equipment may sometimes result in adverse effects on patient. Sometimes malicious or misguided tempering of the equipment by patient or his visitor may also contribute to the adverse incidents.

Examples of faulty device or equipment problems due to different factors have been demonstrated in Table 16.1.

Cyber-security Threats to Health Care Delivery System

These are new threats to health care delivery system especially health IT systems and network connected devices. These types of cyber attacks can prevent the access to

Table 16.1: Examples of faulty device or equipment problems due to different factors

Equipment manufacturing defect
- Breakage of surgical instruments (e.g. needles, scalpel blade)
- Malfunction of equipment (e.g. misfiring of stapler)
- Software failure (monitors and ventilators)
- Electrical or mechanical component failure
- Low battery backup (in transport ventilators and monitors)
- Faulty alarms (in infusion pumps, monitors and ventilators)
- Faulty accessories and consumables of equipment

Operator/clinical team fault
- Lack of knowledge or training regarding particular equipment
- Incorrect use of equipment (e.g. misapplication of forceps or ventouse during labor)
- Alarm fatigue or missed alarms (e.g. missing or ignoring the alarm of ventilators, infusion pumps or monitors in critical care settings)
- Failure to check the equipment settings prior to procedures
- Failure to completely disinfect the instruments before use (faulty disinfection of endoscopes in between uses)
- Incorrect equipment assembly
- Use of equipment for non-indicated purpose
- Continuing a procedure once an equipment problem was evident

Issues related to organisation/hospital
- Lack of utilities such as medical gas, electrical supply and water
- Failure of the health care facility to follow the equipment manufacturer's recommendations for maintenance, cleaning, calibration
- Faulty layout and mounting of equipment
- Failure to report the equipment malfunctions to appropriate authorities
- Incorrect training of users
- Failure to upgrade software and/or hardware

Issues related to the patient
- Tampering of equipment by the patient himself, other patient or their visitors
- Interactions between device and patient (including patient's pathology/physiology) contributing to the event

patient data and records, and affect the functionality of networked medical devices. Such disruptions can lead to damage of equipment and systems, exposure of sensitive data, cancellation of procedures and ultimately resulting in patient harm. Safeguarding practices include:
- Identification, protection and monitoring of all remote access points
- Adherence to recommended cyber-security practices such as strong password, maintenance of health IT system.

Prevention of Medical Error and Medicolegal Issues due to Equipment Failure[4, 5]

It is a common belief that newer medical device or equipment will improve the efficiency, increase quality, and promote safety; however, it may also introduce errors and adverse events resulting in unexpected outcome and increase instances of litigation. There are numerous medical devices that are implanted in patients, multiple pieces of equipment which are used to monitor the patients in critical care centers. Any error or malfunctioning of these devices and equipment may result in life-threatening events.

To prevent this health care workers and institution should take following actions to improve device safety:

- Health care workers should be involved in setting and evaluating institutional, organizational, and public policy related to equipment and device.
- It should be made sure that equipment and device meet the standard criteria for quality, safety and design.
- Institution should have a backup plan for failure of life-sustaining devices (e.g. ventricular assist devices, defibrillators, transport ventilators) and reasonable skill should be exercised in case of equipment failure.
- There should be institutional policies and processes related to maintenance, training, monitoring, and reporting adverse events related to technology.
- Equipment should be sequestered if suspected of failure or defect both to protect other patients and to allow biomedical engineering or the manufacturer to extract valuable data.
- Whenever any equipment or device with new technology is introduced, there should be proper demonstration, training for users and provision of maintenance for device.
- There should be regular assessment after use of equipment because users, environments, and organizations change over time, altering the risk profile.

Adverse Event Reporting for Medical Devices, India[6]

To ensure the quality and to promote the safe use of medical devices, well-structured vigilance system with a robust regulatory framework is essential. As medical equipment failure with unexpected outcome may land into legal problems for health care providers, so a fair adverse event reporting for medical device is needed. Earlier, there was no systematic structure available to collate adverse events associated with medical devices so medical devices were regulated under the Indian Drugs and Cosmetics Act. In July 2015, the Indian health ministry approved the establishment of the materio-vigilance program, with the Indian Pharmacopoeia Commission as the national coordinating centre. In 2017, the government of India issued the Medical Devices Rules, 2017 for regulating medical devices used throughout the country. The Central Drugs Standard Control Organization, under the directorate general of health services of the health ministry is the national regulatory authority responsible for approval of the manufacturing, import, labelling, sale and distribution of medical devices, including *in vitro* diagnostics.

Adverse events caused by medical devices can be reported by health care workers, designated medical device adverse event monitoring centres or any person having direct or indirect knowledge of medical device adverse events. These reports of suspected medical device adverse events are accessed by the Indian Pharmacopoeia Commission. Based on the inputs, core technical committee makes recommendations and Central Drugs Standard Control Organization discusses the recommendations and takes regulatory action if needed.

Regulation of India's Medical Device Quality

The Drugs and Cosmetics Act, 1940 (DCA) regulates the standards of quality and safety of medical devices but it is applied to only those medical devices which are notified by the government from time to time as "drugs".

The Medical Devices Rules, 2017 (MDR)[7] have been framed under DCA. All marketers/importers/manufacturers/sellers of notified medical devices must follow the comprehensive quality requirements laid down by these rules. Under the new rules, medical devices were classified as per Global Harmonization Task Force (GHTF) practice based on associated risks as follows:

- Class A (low risk)
- Class B (low and moderate risk)
- Class C (moderate and high risk)
- Class D (high risk)

These rules laid down risk proportionate regulatory requirements to be fulfilled by manufacturer and these were based on best international practices.

The Medical Device (Amendment) Rules, 2020: The government had notified 37 categories of medical devices as drugs till February 11, 2020. The Medical Device (Amendment) Rules, 2020 ("MDR Amendment") were notified by Indian government on February 11, 2020 to include all other remaining medical devices as "drug" under the DCA and MDR.

Now, all medical devices sold in India are under the control of DCA and MDR from April 1, 2020. Two changes were introduced to MDR by these modifications. A new chapter is formed for registration of newly notified medical devices by their respective manufacturers and importers. The new registration number obtained by the manufacturer and importer will be displayed on their label. In another change, 37 categories of already regulated or notified medical devices are exempted from the requirement of registration introduced by the new chapter.

Liability of Adverse Issues Related to Medical Equipment

Same principles of medical negligence also apply to fix the liability of adverse issues related to medical equipment. Medicolegal issues arise when a patient suffers an injury as a result of a defective medical device or the result of negligence of the medical professional in using of the device and there should be existence of duty of care between patient and medical professional or hospital.

Liability of a user or medical practitioner: A medical practitioner may be held liable for equipment failure due to user-related errors. To prove the medical negligence of medical practitioner in using the medical device there should be:

- Presence of legal duty to treat the patient
- Breach of such legal duty in comparison to the expected performance of the people from the same expertise. It should be obvious that equipment failure occurred due to gross lack of necessary skill or expertise of medical professional that he is supposed to possess.
- Presence of injury to the patient as a direct consequence of faulty device or equipment.

In the case of 'Mohd Abrar vs Dr Ashok Desai,[8] the appellant suffered comminuted fracture of left leg due to accident and external fixator was applied by the defendant. He complained that the external fixator was inferior and defective and the rings and steel rods were rusted. He developed gangrene of left leg due to defective fixator resulting in amputation of left leg below the knee. It was held that professional negligence is not established against the respondent so he was not liable as it was

difficult to draw a thin line between negligence of the patient, the quantum of his contribution and other causes which gave rise to the onset of gangrene and absence of care on the part of the doctor.

In another case of 'Raghavendra Anantrai Mehta vs Dr Darshan Jhala,[9] complainant developed cardiac rhythm disturbance for which he was implanted with a permanent pacemaker (PPM) by the cardiologist. On 3rd day of implantation, rhythm disturbance was detected again and it was rectified with reprogramming and repositioning of PPM by the opponent. In follow-up, complainant again developed same problem and he was operated again for repositioning of the lead of PPM in another hospital. Complainant alleged in state consumer disputes redressal commission that there was medical negligence on the part of cardiologist while doing implantation of PPM. State commission did not find cardiologist negligent as dislodgment of lead is known complication of PPM implantation and cardiologist recognized it efficiently and advised to correct it. Complainant failed to prove medical negligence on the part of cardiologist.

Liability of Institution/Hospital in Equipment Failure

The liability of a hospital in cases of medical negligence could be direct or vicarious.

Direct Liability

Direct liability of hospital arises when hospital fails to provide the proper infrastructure (electrical supply, medical gases, training for users) and maintenance services resulting in failure of equipment leading to harm or injury to patient.

Vicarious Liability

If any adverse incident related to equipment occurs in a hospital due to error of the health worker or physician who is employee of that hospital, hospital may be held liable for the fault of its employee. There must be clear breach of duty of care resulting in injury to the patient.

In the case of 'St. Antony Hospital vs C.L. D'Silva[10]; patient was operated for ovarian cyst removal with the help of laparoscope by the visiting doctor from US. During the surgery there was colonic tear resulting in peritonitis and sepsis. Exploratory laparotomy was performed to rectify the condition of patient and referred to another hospital for further management where patient passed away. In state consumer disputes redressal commission, it was proved that laparoscope was borrowed from another hospital and it was not working properly during operation leading to tear of colon and consequent complications. So, hospital was held liable for negligence and deficiency in service. It was proved that it was not checked before surgery whether the laparoscopy equipment was working and not defective.

Liability of Manufacturer

Manufacturer may be held liable if it is proved that injury to the patient occurred due to manufacturing defect or manufacturing design error in equipment and the medical practitioner worked with reasonable skills. In India, the manufacturer, distributor and retailer can be held liable and punished under DCA, 1940 or under the Indian Penal Code, 1860 (IPC) for manufacturing, importing and selling of devices or drugs that are not authentic, or are of low quality or breach any of the requirements of law.

There is also provision of liability and compensation under the Consumer Protection Act, 2018 for manufacturer and retailer of lower quality defective goods. There can be application of the concept of 'misbranded', 'adulterated' and 'spurious' for medical devices also under DCA, 1940.

In the case of 'Kailash Hospital and Research Centre vs Prem Tandon,[11] the complainant suffered an accident, surgery was done and a rod was implanted in his leg. As the patient started to mobilize the rod was broken. So, another surgery was done to remove broken rod and replace it with another rod by another doctor. The National Commission held that a specific case of medical negligence has to be made out/spelled out by the complainant, and, the onus of proof is on the complainant to prove this medical negligence by an expert-opinion. The onus is on the complainant, to prove, that as to what the doctor should have done which he did not do, or, what the doctor did not do what he ought to have done? Admittedly, no opinion of any expert has been led in this case by the complainant so the doctor was not held liable.

In this case, although the implanted rod was broken within 5 months but no issue was raised on quality of rod or its manufacturing defect.

In India, issues are still not raised on the manufacturing defects of the equipment by the plaintiffs.[12] The only issue raised is the liability of doctors as a user in most of the cases. While in US, whenever a patient is suffered due to faulty device or equipment failure, manufacturer has been held liable. There is no issue raised with regard to the liability of physician in case of faulty device unless it is directly related to the error in use of equipment.

Key Points

- Medical equipment is an integral part of health care delivery system and helps in diagnosis, managements and prevention of ailments.
- Failure or defect in medical equipment in different settings such as critical care, operation theatre or delivery rooms may cause harm to patient's health leading to medicolegal implications.
- The main causes of equipment failure are manufacturing defect in equipment, its design and user-related errors along with faulty maintenance practices by the organisation.
- A user or a physician can be held liable for equipment failure if there is breach in duty of care and lack of reasonable skill while using the equipment or device resulting in harm or injury to the patient.
- Although manufacturer can be held liable for any manufacturing defect of equipment/device but this issue is not raised by the plaintiff most of the time in India.

What's New

- Ransom-ware and other cyber-security threats to health care delivery systems are implicated as new cause for medical devices related adverse incidents. If information technology (IT) is being used in delivering health care then there should be effective protection and monitoring of remote access system.
- In India with the introduction of new Medical Device Rules and its amendments, it is necessary to register the medical device for all the manufacturers and importers.

REFERENCES

1. Medical devices definition. Ministry of Health and Family Welfare. Available at: https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NTU0OA== Accessed on 29 April 2020.
2. Amoore JN. A Structured Approach for Investigating the Causes of Medical Device Adverse Events. *J Med Eng* 2014; 2014: 314138.
3. Fairbanks RJ, Wears RL. Hazards with medical devices: the role of design. *Annals of Emergency Medicine* 2008; 52(5): 519–21.
4. Mattox E. Medical devices and patient safety. *Crit Care Nurse* 2012; 32(4): 60–68.
5. Rodziewicz TL, Hipskind JE. Medical Error Prevention. StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2020. Available at: https://www.ncbi.nlm.nih.gov/pubmed/29763131. Accessed on 29 april 2020.
6. Shukla S, Gupta M, Pandit S, Thomson M, Shivhare A, Kalaiselvan V, et al. Implementation of adverse event reporting for medical devices, India. *Bull World Health Organ* 2020; 98(3):206–211.
7. Medical Device Rules notification 2017. Ministry of Health and Family Welfare. Available at: https://cpdm.iisc.ac.in/utsaah/wp-content/uploads/2016/07/GOI_MedicalDeviceRules_notificationJan2017_eng.pdf Accessed on 29 April 2020.
8. Mohd Abrar vs Dr Ashok Desai and others. Decided on 8 April, 2011 by National Consumer Disputes Redressal. Available at: https://indiankanoon.org/doc/170012409/ Accessed on 7 May, 2020.
9. Raghavendra Anantrai Mehta vs Dr Darshan Jhala. Decided on 1 June, 2010 by State Consumer Disputes Redressal Commission. Available at: https://indiankanoon.org/doc/43303670/ Accessed on 7 May 2020.
10. St. Antony Hospital vs C.L. D'Silva. Decided on 2 April, 2013 by National Consumer Disputes Redressal. Available at: https://indiankanoon.org/doc/18286818/ Accessed on 7 May 2020.
11. Kailash Hospital vs Prem Tondon and others. Decided on 7 January, 2010 by National Consumer Disputes Redressal Commission. Available at: https://indiankanoon.org/doc/49687530/ Accessed on 7 May 2020.
12. Chakrabarti, N., & Chatterjee, S. Regulating health-related technologies and medical devices: With special reference to india 2014, *Journal of the Indian Law Institute*, 2014; 56(2), 216–35. Available at: www.jstor.org/stable/43953702 Accessed on 10 May 2020.

Chapter

17

Unexpected Congenital Anomalies/ Birth Asphyxia

VK Goyal

INTRODUCTION

Congenital anomalies are a major cause of stillbirths and neonatal mortality. Not all congenital abnormalities can be detected by routine screening. The primary reason for litigation in this area is failure to offer termination of pregnancy as a result of failure to diagnose a problem.

Incidence

The most common reasons for dispute in obstetrics were, perinatal asphyxia (50%), traumatic injuries of the newborn (24%), maternal sequelae (19%) and issues related to prenatal diagnosis and/or obstetric ultrasound (5.4%).

Advances in ultrasonography equipment and technique allow early detection of many congenital malformations. In addition, genetic testing can be performed in a prenatal setting on a variety of biological samples obtained by invasive and non-invasive procedures. This has increased the expectations of the public to the unrealistic levels.

UNEXPECTED CONGENITAL ANOMALIES

The widespread use of ultrasound has led to the erroneous belief among much of the population that all major and many minor structural fetal abnormalities can be detected before birth. Numerous large studies have provided rather disappointing overall detection rates of as low as 13–16%, although others have demonstrated much higher rates (up to 85%).

LIMITATIONS OF SCREENING

Although routine screening for fetal abnormalities is, indeed, very successful overall, there are limitations to the abilities of both the technique and the operators to detect every anomaly. There are several reasons for this: Not all anomalies (e.g. some cardiac, gastrointestinal and renal abnormalities) are evident at 20 weeks, when the routine ultrasound examination for anomalies is performed; there is wide variation in both expertise of staff and quality of equipment; and some fetuses are difficult to scan because of maternal habitus, reduction in liquor volume or persistent difficult position. There are very few structural abnormalities for which the detection rate approaches 100%.

Major malformations such as anencephaly are rarely missed on routine ultrasound. However, prenatal diagnosis of some abnormalities depends on the screening program used locally. For example, duodenal atresia (which may be associated with trisomy 21) is not usually apparent on ultrasound if performed at 18–22 weeks of gestation. If the locally available screening for congenital heart defects is limited to examination of the four-chamber view of the fetal heart, major abnormalities such as transposition of the great arteries and tetralogy of Fallot will not be detected. Anal and rectal atresia are not amenable to prenatal diagnosis, nor are many dysmorphic features such as low-set ears. Isolated cleft palates are extremely difficult to identify, although the detection rate of cleft lips can be high if the face is routinely examined. Some brain malformations such as neuronal migration disorders cannot be detected using ultrasound and require magnetic resonance imaging for their diagnosis. Other conditions that are described as congenital abnormalities may be normal in fetal life but abnormal if they persist after birth, such as patent ductus arteriosus. Similarly, because of the presence of the foramen ovale in the intra-atrial septum of the fetal heart, it is extremely difficult to detect atrial septal defects that will persist after birth. Therefore, although these will be counted as congenital abnormalities, they may either be normal or undetectable on fetal ultrasound.

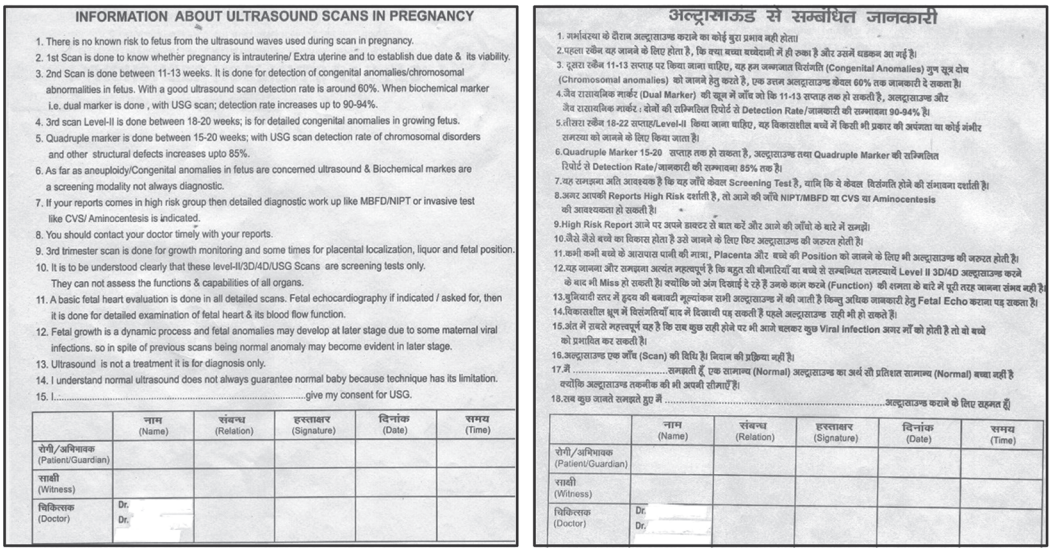
Preventive Steps

1. Follow a standard protocol/guidelines for detailed ultrasound and give its reference in the report.
2. Always take prior consent for all ANC ultrasounds explaining that congenital anomaly may be missed (consent form attached) (Fig. 17.1).
3. If there is difficulty in obtaining adequate ultrasound views it must be noted and explained to the mother and attendants.' This must be clearly recorded.
4. Counselling of the the patient and attendants at each visit about the shortcoming of sonology.
5. If anomaly is detected at any stage, refer the patient to the centre with proper facilities.
6. Never refrain in advising further tests as MRI, detailed fetal echocardiography, 3D, 4D scan and other blood tests in case of doubt.
7. Always keep the team approach
8. Never feel shy to ask for 2nd opinion.
9. If patient is not following your advice, write on patient prescription and get it signed.
10. Specify the appropriate gestation in detailed ultrasound scan on very first visit, AN visit and give patient education material.

Damage Control

When a baby with an unexpected abnormality is born, it is essential that those involved in the care of the baby and parents understand why that diagnosis might have been missed:

1. Never make the rash statements such as: 'I cannot understand how the scan missed that', or why the amniocentesis was not offered to you.
2. After proper counselling refer the newborn to well equipped centre for proper care.



INFORMATION ABOUT ULTRASOUND SCANS IN PREGNANCY

1. There is no known risk to fetus from the ultrasound waves used during scan in pregnancy.
2. 1st Scan is done to know whether pregnancy is intrauterine/ Extra uterine and to establish due date & its viability.
3. 2nd Scan is done between 11-13 weeks. It is done for detection of congenital anomalies/chromosomal abnormalities in fetus. With a good ultrasound scan detection rate is around 60%. When biochemical marker i.e. dual marker is done , with USG scan; detection rate increases up to 90-94%.
4. 3rd scan Level-II is done between 18-20 weeks; is for detailed congenital anomalies in growing fetus.
5. Quadruple marker is done between 15-20 weeks; with USG scan detection rate of chromosomal disorders and other structural defects increases upto 85%.
6. As far as aneuploidy/Congenital anomalies in fetus are concerned ultrasound & Biochemical markes are a screening modality not always diagnostic.
7. If your reports comes in high risk group then detailed diagnostic work up like MBFD/NIPT or invasive test like CVS/ Aminocentesis is indicated.
8. You should contact your doctor timely with your reports.
9. 3rd trimester scan is done for growth monitoring and some times for placental localization, liquor and fetal position.
10. It is to be understood clearly that these level-II/3D/4D/USG Scans are screening tests only. They can not assess the functions & capabilities of all organs.
11. A basic fetal heart evaluation is done in all detailed scans. Fetal echocardiography if indicated / asked for, then it is done for detailed examination of fetal heart & its blood flow function.
12. Fetal growth is a dynamic process and fetal anomalies may develop at later stage due to some maternal viral infections. so in spite of previous scans being normal anomaly may become evident in later stage.
13. Ultrasound is not a treatment it is for diagnosis only.
14. I understand normal ultrasound does not always guarantee normal baby because technique has its limitation.
15. I.....give my consent for USG.

	नाम (Name)	संबन्ध (Relation)	हस्ताक्षर (Signature)	दिनांक (Date)	समय (Time)
रोगी/अभिभावक (Patient/Guardian)					
साक्षी (Witness)					
चिकित्सक (Doctor)	Dr. Dr.				

अल्ट्रासाऊंड से सम्बंधित जानकारी

1. गर्भावस्था के दौरान अल्ट्रासाउन्ड कराने का कोई बुरा प्रभाव नही होता।
2. पहला स्कैन यह जानने के लिए होता है, कि क्या बच्चा बच्चेदानी में ही रुका है और उसमें धड़कन आ गई है।
3. दूसरा स्कैन 11-13 सप्ताह पर किया जाना चाहिए, यह हम जन्मजात विसंगति (Congenital Anomalies) गुण सूत्र दोष (Chromosomal anomalies) को जानने हेतु करते है, एक उत्तम अल्ट्रासाउन्ड केवल 60% तक जानकारी दे सकता है।
4. जैव रासायनिक मार्कर (Dual Marker) यदि खून में जाँच जो कि 11-13 सप्ताह तक हो सकती है, अल्ट्रासाउन्ड और जैव रासायनिक मार्कर : दोनों की सम्मिलित रिपोर्ट से Detection Rate/जानकारी की सम्भावना 90-94% है।
5. तीसरा स्कैन 18-22 सप्ताह/Level-II किया जाना चाहिए, यह विकासशील बच्चे में किसी भी प्रकार की अपंगता या कोई गंभीर समस्या को जानने के लिए किया जाता है।
6. Quadruple Marker 15-20 सप्ताह तक हो सकता है, अल्ट्रासाउन्ड तथा Quadruple Marker की सम्मिलित रिपोर्ट से Detection Rate/जानकारी की सम्भावना 85% तक है।
7. यह समझना अति आवश्यक है कि यह जाँचे केवल Screening Test है, यानि कि ये केवल विसंगति होने की संभावना दर्शाती है।
8. अगर आपकी Reports High Risk दर्शाती है, तो आगे की जाँचे NIPT/MBFD या CVS या Aminocentesis की आवश्यकता हो सकती है।
9. High Risk Report आने पर अपने डाक्टर से बात करें और आगे की जाँचो के बारे में समझें।
10. जैसे जैसे बच्चे का विकास होता है उसे जानने के लिए फिर अल्ट्रासाउन्ड की जरुरत होती है।
11. कभी कभी बच्चे के आसपास पानी की मात्रा, Placenta और बच्चे की Position को जानने के लिए भी अल्ट्रासाउन्ड की जरुरत होती है।
12. यह जानना और समझना अत्यंत महत्वपूर्ण है कि बहुत सी बीमारियाँ या बच्चे से सम्बन्धित समस्यायें Level II 3D/4D अल्ट्रासाउन्ड करने के बाद भी Miss हो सकती है। क्योंकि जो अंग दिखाई दे रहे हैं उनके काम करने (Function) की क्षमता के बारे में पूरी तरह जानना संभव नही है।
13. बुनियादी स्तर में हृदय की बनावटी मूल्यांकन सभी अल्ट्रासाउन्ड में की जाती है किन्तु अधिक जानकारी हेतु Fetal Echo कराना पड़ सकता है।
14. विकासशील भ्रूण में विसंगतियाँ बाद में दिखायी पड़ सकती हैं पहले अल्ट्रासाउन्ड सही भी हो सकते हैं।
15. अंत में सबसे महत्वपूर्ण यह है कि सब कुछ सही होने पर भी आगे चलकर कुछ Viral Infection अगर माँ को होती है तो वो बच्चे को प्रभावित कर सकती है।
16. अल्ट्रासाउन्ड एक जाँच (Scan) की विधि है। निदान की प्रक्रिया नही है।
17. मैं.....समझती हूँ, एक सामान्य (Normal) अल्ट्रासाउन्ड का अर्थ सौ प्रतिशत सामान्य (Normal) बच्चा नही है क्योंकि अल्ट्रासाउन्ड तकनीक की भी अपनी सीमाएँ हैं।
18. सब कुछ जानते समझते हुए मैं .....अल्ट्रासाउन्ड कराने के लिए सहमत हूँ।

	नाम (Name)	संबन्ध (Relation)	हस्ताक्षर (Signature)	दिनांक (Date)	समय (Time)
रोगी/अभिभावक (Patient/Guardian)					
साक्षी (Witness)					
चिकित्सक (Doctor)	Dr. Dr.				

Fig. 17.1: Information about ultrasound scans in pregnancy

Case Scenario

Different judgments have been awarded in various different courts, some of them are been reproduced here:

Hon'ble Supreme Court, **Senthil Scan Centre vs Shanthi Sridharan and another, III (2011) CPJ 54 (SC)**, held as follows:

"Ultrasound is not a perfect depiction of the foetus and the scan result cannot be 100% conclusive. It is often difficult to examine some foetal areas. Difficulties may also be posed by the relative paucity of amniotic fluid in the third trimester, the hyper-flexed position of the fetus, engagement of the head or compression of some fetal parts."

State Consumer Disputes Redressal Commission, Delhi: Archana vs Tarun Kumar Vohra on 22 September, 2011: Patient with regular antenatal scans delivered male child with no left upper limb. The experts report that ultrasound is not a 100% foolproof method to diagnose congenital anomalies and that the limitation of fetus can be effected by amniotic band syndrome and at any time during the period of pregnancy. Court said—in the case in hand the experts report takes back seat, as the case appears to be squarely covered by the principle of res-ipsa-loquitur.

State Consumer Disputes Redressal Commission: Jincy Mathew, M.S. Mathew vs Dr G.V. Kalaichelvi, G.V.K. Hospital on 26 May, 2015, Tamil Nadu: A boy was delivered suffering from hemimelia with the left forearm absent, a congenital limb anomaly. Here the State Consumer Forum write there is no sufficient evidence to decide the issue whether there is any negligence or deficiency in service on the part of the opposite party/ultrasonologist and we cannot come to proper conclusion, without the expert's opinion or evidence. Further the doctrine of res ipsa loquitur has no application at all to the instant case.

National Consumer Disputes Redressal: Anil Dutt and another vs Vishesh Hospital and others on 16 May, 2016: Newborn delivered with left arm and kidney

missing and even lungs were not completely developed. USG report at 20 weeks was normal. As per expert, any amount of detailed study by ultrasonography, may miss the congenital anomaly at the expert hands and cannot amount to negligence with availability of even ultra-modern equipment.

Opinion given by another committee of three experts said, sonologists cannot control maternal body habitus, time of examination, amount of liquor of fetal position which may dramatically alter the ability to diagnose fetal anomaly. It is not always possible to detect all congenital abnormalities.

The committee put reliance upon Callen's book and opined that it is not always possible to detect all congenital anomalies.

Court observed that, experts relied upon routine OBG scan vs targeted scan, but silent about the ethical obligations of sonologist.

Court further said that, if a malformation is suspected, and the examiner has had little experience with the abnormality in question, the case should be referred to a more experienced examiner. Only in this way all patients be served best.

The court said the principle of *res ipsa loqiutur* is squarely applicable in this case. Compensation awarded.

BIRTH ASPHYXIA

Introduction

Birth asphyxia has been defined as "a condition of impaired blood gas exchange, leading, if it persists, to progressive hypoxemia and hypercapnia."

Perinatal asphyxia is a lack of blood flow or gas exchange to or from the fetus in the period immediately before, during, or after the birth process. Perinatal asphyxia can result in profound systemic and neurologic sequelae due to decreased blood flow and/or oxygen to a fetus or infant during the peripartum period.

Incidence

Perinatal asphyxia has an incidence of 1–6 per 1000 live births. Obstetric litigation is a growing problem in developed countries and its escalating cost together with increasing medical insurance premiums is a major concern for maternity service providers, leading to obstetric practice cessation by many practitioners. Fifty-four (54%) to 74% of claims are based on cardiotocographic (CTG) abnormalities and their interpretation followed by inappropriate or delayed reactions.

During litigation procedures, it is necessary to have access to a readable CTG, a well-documented partogram, a complete analysis of umbilical cord gases, a placental pathology and an extensive clinical work-up of the newborn infant including cerebral MRI. Malpractice litigation in obstetric care can be reduced by permanent CTG education, respect of national CTG guidelines, use of adjuncts such as fetal blood sampling for pH or lactates, considering the fast occurrence of fetal cerebral hypoxic injuries, and thus despite an adequate management, many intrapartum asphyxias will not be preventable.

By the way, when cases are particularly delicate, especially in civil courts, it is necessary to finely distinguish concomitant causes between human and natural ones,

then natural causes between preventable and unpreventable ones; not limited to the simple assessment whether it is an antepartum or intrapartum onset but regarding the promptness of procedures performed by all the health assistance personnel too.

A significant proportion of obstetric and neonatal malpractice litigation alleges that neonatal brain injury and subsequent neurologic disability, i.e. cerebral palsy, epilepsy, and mental retardation arises from the negligence of health care providers during the pregnancy, labor, delivery and/or immediate neonatal period.

The often, long delay between the filing of a complaint and the commencement of a medical malpractice lawsuit underlines the need for comprehensive and meticulous record keeping. The importance of appropriate communication between doctor and parents cannot be over-emphasized.

This emphasizes the need for careful and complete documentation that can be retrieved at a later date if needed in order to produce a reliable medical report.

Preventive Steps

1. All antenatal patients should be counselled, that outcome cannot be guaranteed.
2. High risk patients to be categorised during antenatal visits and risk factor should be clearly explained and documented.
3. If the centre is not well equipped to deal with high risk newborns, early antenatal referral is the best.
4. All deliveries to be attended by qualified pediatrician.
5. All pieces of working neonatal resuscitation equipment, drugs, oxygen to checked well prior to the event.
6. Meticulous notes of the progress of labour and neonatal resuscitation should be written, with date, time, signature and name before leaving the place.
7. If patient is not willing for operative procedure get the negative consent.

Damage Control

1. In the event of unexpected birth asphyxia, communicate the events timely, explain clearly the condition of the baby and resuscitative measures going on. Communication/counselling to be done by responsible person.
2. If setup is not well equipped, timely referral to higher centre is important after proper stabilisation and communication with that centre.
3. Keep your cool if attendants are aggressive.

Case Scenario

National Consumer Disputes Redressal: Baby Geetha and others vs Cosmopolitan Hospitals (P) Ltd. ... on 18 May, 2006, equivalent citations: 3 (2006) CPJ 89 NC: Pediatrician attended baby only half an hour after the birth. Later in ward baby was having some abnormal activity, that was not taken care of.

Court observed this case clearly fall under the doctrine of res ipsa loquitur. Compensation awarded.

National Consumer Disputes Redressal: Smt Radhika Rakesh Nigam vs Dr (Mrs) Swaraj Naik on 17 October, 2011: Pediatrician attended the delivery, asphyxiated

baby delivered. During labour patient was prescribed contramal (Tramadol) injection. Professional medical opinion holding that administration of this analgesic is unlikely to have caused respiratory distress in the neonate leading to birth asphyxia as in this case. Case dismissed

National Consumer Disputes Redressal: Deep Nursing Home vs Manmeet Singh Mattewal on 9 May, 2012: Labour record shows that FHS was normal till delivery; Asphyxiated baby delivered. Court Conclusion, the resuscitation measures taken by attending paediatrician are according to standard protocol/guidelines. The cause of severe birth asphyxia cannot be determined without autopsy of the baby. Case dismissed.

National Consumer Disputes Redressal: Dr (Mrs) Indu Sharma vs Indraprastha Apollo Hospital on 22 April, 2015: Precious pregnancy, asphyxiated baby delivered by LSCS in reputed tertiary care hospital.

Court observations, it was the duty of obstetrician to counsel the patient properly about the progression of labour for every 2 hours. Syntocinon to be given via infusion pump. Storage of CTG CTGs should be stored for at least 25 years and the hospital should make adequate provision for safe storage and easy retrieval.

Court further said that we also reject the contention of OP that, the patient was reluctant to undergo C-section, doctor would not just blindly obey the wishes of the patient.,

OP failed to take written consent or signature of the complainant or her husband about refusal of C-section (negative consent is very important). Huge compensation awarded.

State Consumer Disputes Redressal Commission: Sunita Kumar and another vs St. Stephen Hospital on 8 May, 2019: Baby delivered with birth asphyxia, properly and timely managed by the pediatrician. Hospital produced all the delivery and neonatal resuscitation notes. Court observed, negligence as alleged against the treating doctor or OP hospital could not be substantiated. Case dismissed.

Key Message

It would be best for ultrasonologist to have written consent from the patient that U/S is not a 100% fool proof method for detection of congenital anomalies.

Explain clearly that pregnancy is a ongoing process and the things which were normal earlier may become abnormal at later stage of pregnancy.

Always have the indemnity insurance as expert opinions are been discarded number of times.

If delivery process is been delayed, proper regular counselling is very important.

If baby is unexpectedly asphyxiated, inform the attendants' immediately.

Section

4

Difficult Situations

18. Sudden Death in Ward/OPD
19. Violent Mob, Uncooperative, Aggressive Patient or Relative
20. Facing Electronic, Social and Print Media

Section Editors: Sashimohan Sardana, Charu Mittal

Chapter
18

Sudden Death in Ward/OPD

Anurag Verma

All hospitals, one or the other day face difficult situations, anticipated or unexpected. The difficult situations can diffuse easily or may take turn for bad.

In a small proprietary hospital, the consultant has to deal directly with such situations and may face problems.

Sudden death is unexpected instantaneous death within twenty four hours of onset of symptoms, with or without pre-existing conditions and there are no accidental or criminal causes.

Various causes of sudden death can be classified according to different anatomical systems of the body.

1. Cardiovascular system:
   a. IHD. In extreme cases, heart stops suddenly, in less extreme cases heart fails.
   b. Cardiac temponade.
   c. Hypertensive heart disease.
   d. Aortic valve disease.
   e. HOCM (hypertrophic obstructive cardiomyopathy)
2. Respiratory system: Can be because of pulmonary embolism, hemorrhage in air passages, pneumothorax, status asthmaticus.
3. Gastrointestinal system: Massive bleed from gastroduodenal ulcer, esophageal varices.
4. Gynecological conditions. Ruptured ectopic pregnancy, premature separation of placenta previa, illegal abortion.
5. CNS: Nearly always by hemorrhage within brain, meninges.
6. Circulatory nonhemorrhagic causes: Central thrombus in one of the cerebral arteries at base of the brain usually with a plaque of atherosclerosis. Second unusual cause is central embolism.
7. Epilepsy: Prolonged single seizure in status epilepticus, death is because of asphysia, regurgitation of contents in airways and obstruction by tongue.
8. Unknown

Sudden death is due to shock which has different underlying causes:

- Hemorrhagic shock
- Neurogenic shock
- Cardiogenic shock
- Endotoxic shock
- Anaphylactic shock

Sudden death usually happens to be unattended by treating physician and nursing staff and is invariably witnessed by the family members or attendants of the deceased. It is a shock to the family and is equally shocking to the treating doctor. Efforts are usually made by treating doctor or nursing staff to save life of the patient on the site in the ward with whatever available resources.

BREAKING THE BAD NEWS TO THE ATTENDANTS[1]

Breaking the bad news to the attendants of the patient needs special skill on the part of clinicians. The doctors depend on their own experience rather than any training received in the medical college. Breaking this bad news shall be done in a better way by a doctor who is specifically trained for it. It is high time to include this subject into the undergraduate medical curriculum. Relatives of the patient are not prepared to face and bear the emotional trauma of bearing unexpected death of their patient. If they are not dealt with caution keeping mind their state of highly volatile emotionally which can lead to sudden outburst in form of anger and violent behavior, shall not be at all desirable. In this situation doctors and the staff should show empathetic attitude with the attendants of the diseased patient which is of prime importance at this point of time otherwise events may take an undesirable turn towards violence as a result of outbursts of emotional reaction from the attendants. Any such event can be avoided by cautious approach by the doctor and the staff of empathy and compassion towards the attendants.

Any unexpected death of the patient is perceived by relatives as untimely and unwarranted. It is an experience of just like a shock to them which at most times they are not able to cope with all of a sudden. It is a natural reaction and should be recognized and tolerated.

It is followed by a reaction of anger which may be directed towards other attendant, staff or any other person. This feeling of anger gradually diminishes once the situation is accepted by the attendants. At this point of time medical staff and doctor should try at their best to console the attendants which shall be helpful to mitigate any feeling of self blaming also from the attendants.

At this point every effort should be done to convince the family members about the reasons which are thought to be most likely to lead to the unexpected death of the patient.

It is true and natural that in event of sudden unexpected deterioration of condition of patient, doctor and medical staff put every possible effort to save life of the patient but at the same time it is also important that family members of the patient should also be apprised of about the unexpected event and all efforts which are being done by the medical team so that there is no possibility for them to blame the medical staff for any negligence after death of the patient. It is very important as leaving aside their own shortcomings after death of patient usually attendants try to find negligence on part of the doctor. When everything possible which can be done is being done, and they know about seriousness of the situation, it is a bit easier to prepare them mentally to face the situation in event of death of the patient.

To effectively deal with this important situation of sudden death of patient, every hospital must have a standard operating procedure which may be as suggested here.

Suggested Measures and Plan of Action to Deal with Situation of Sudden Death

1. There should be a coded alarm system in hospital to alert every staff member and security and call on mobile of every medical staff who is required to reach the site of the incident urgently.
2. Once the doctor on duty has reached at the bed side along with nursing staff, they should patiently and empathically listen to the attendants while minutely examining the patient, trying to ascertain cause of death and treatment being given in a minimum possible time.
3. Bed should be cordoned off if it is a general ward by curtain.
4. Emergency tray containing all the necessary drugs and instruments should be readily available from the nursing station.
5. All the attendants should be requested to leave the ward or room politely except one or two sensible looking ones.
6. Measures for resuscitation of the patient should be started at the bed side itself with artificial respiration by Ambu bag and by drugs through IV line.
7. Now patient should be taken to ICU while the resuscitation is continuing.
8. While resuscitating the patient, doctor and the staff should simultaneously maintain proper recording of the measures being done to revive the patient as in the event of death of the patient if police is called then police shall seize all the records and at that time it shall be difficult to fulfill the records and to prove in court that proper efforts were done, as per law what has been documented has been done and what has not been documented has not been done.
9. While patient is being managed, attendants should also be briefed about condition of the patient to allay their anxiety, to be aware of the situation and to be prepared mentally to face undesirable eventuality.

Suggested Plan to Deal with Attendants of the Patient

a. A senior doctor preferably doctor in-charge if present at that time, should inform to attendants about condition of the patient. Doctor should talk to them in a separate room in a comfortable and calm atmosphere. Doctor should tell them about the probable causes of sudden deterioration of condition of the patient and about prompt treatment which was started in ward itself if patient was shifted from there and about the latest status of health of the patient. Doctor should try to satisfy the relatives if there is any query regarding recovery of the patient is concerned with an empathetic attitude but at the same time he/she should be realistic as much as possible at that point of time so that attendants should be able to accept the outcome in event of death of the patient. Doctor should avoid any chance of confrontation with the relatives if there is any allegation of negligence on part of doctor or staff is there.

b. If attendants of patient want to see patient being treated in ICU, identity of the attendants and their relation with the patient should be confirmed before allowing them to enter ICU and an experienced member of the team should receive them. While measures to stabilize the patient are in progress one of the team members should apprise the attendants about the efforts being carried out. When whatever is being done to save life of the patient explained sincerely to the attendants, they will understand and accept it.

c. There should be a provision of a quiet and comfortable room for discussion about the condition of the patient and one or two members of the family should be there. Purpose of interaction with attendants at this point should be to mentally prepare them for possible event of death of the patient also.

   At this time a senior doctor is preferable, he should introduce himself and explain the possible reasons of sudden deterioration of patient's condition. While after being explained about the possible reasons of worsening of patient's condition and treatment being carried out, doctor should explain about the prognosis and chances of survival.

   Attendants should be informed regularly from time to time about the process of resuscitation, this shall make them satisfied as per the efforts of the doctors and staff to save the patient and they can prepare themselves for any bad news also.

d. In event of death of the patient where efforts to revive the patient have failed, doctor in-charge of the patient if he was present, should communicate with relatives to inform about the bad news.

   It is advisable to talk to the relative who had given the consent and who was briefed by the doctor from time to time about progress or health status of the patient. Number of relatives at this time should be as less as possible as it shall be easier to satisfy them. It is a natural reaction that when they shall come to know about death of patient there may be a sudden outburst of emotions more than usually expected, in that case they may blame again the doctor and staff for some negligence and if not pacified at that very point of time, they may take it as cause of death of the patient and can be over assertive of that, it is very important to counteract that allegation and to save the medical team from any wrong implications. Sometimes it also becomes prudent to let the relatives understand that neither the medical team nor the attendants are responsible for the unfortunate outcome, this shall relieve the attendants from any sense of self blame or guilt. They should be convinced that there was no deficiency in efforts either from the medical staff or from their side.

   At this time every effort of the doctor should be to satisfy the attendants in a modest way for their genuine and factual queries and to best avoid any argument if they blame doctor or staff solely, any provocation at this time should be best avoided.

   When attendants are consoled and immediate spurt of emotions is a bit cooled off, they should be allowed to see body of the patient. In the meantime when communication with attendants is going on, dead body of the patient should be made presentable. All signs of the efforts which may seem unpleasant to the non medical people who are not used to see signs of intervention with instruments, e.g. endotracheal tube, catheters, etc. should be removed.

   Any spots of blood, jelly used for ECG or stains of vomitus, etc. should be properly cleaned, and body should be properly covered with clean bed sheet.

   Medical team should be well prepared to manage any reaction of neurogenic origin in attendants of labile psyche or any vasovagal reaction.

e. If patient dies in ICU despite all efforts to resuscitate patient, then also as described earlier, a senior doctor of the team should communicate with the attendants in same way as described earlier in a calm and quiet room. He should explain all

efforts done to save the patient and let them know about the bad outcome in an empathetic way. As described earlier there may be an outburst of grief reaction which should be tackled wisely by the medical team. Family members of the diseased should be assisted to see the diseased in same manner as described earlier while visiting the patient being resuscitated.

After relatives become stable emotionally or they want to take the body home, one of the staff members should be deputed to assist them for completing the formalities related with bills payment, transportation or for autopsy if needed.

f. While doing sincere efforts to save life of the patient, doctors should also keep in mind that relationship between doctor and patient has changed from fiduciary to a relationship of service provider and consumer and any shortcoming on part of the doctor can be construed as a negligence by the attendants and they may try to take advantage of it, at the first instance to get the bills waived off and they may go up to the extent of demanding compensation for any negligence alleged by them.

Along with doing all efforts to save life of the patient, doctor and staff should keep following points in mind.

1. Doctor should not show surprise or as an unexpected event happened, he should take the situation to be tackled with responsibility and a situation of challenge arising out of the course of the disease process. He should be looking concerned to the patient and attentive at same time to any relevant query of the attendants so that they are satisfied and cannot blame him for any gesture of apathy and not paying due attention at the time of emergency.
2. Doctor must avoid to fire at the staff at this time, any mistakes by the staff even if trivial shall be taken as sole reason for the mishappening with the patient and the genuine efforts of them shall be viewed as doing the patchwork. Doctor should be very calm and medical team should maintain balance between starting resuscitation of the patient and at the same time satisfying the attendants.
3. While initiating resuscitation doctor should not bluntly avoid attendants so as to appear to be dominating wrongly, avoiding genuine queries of attendants may be taken as doctor to be confused himself. At this point medical team should be very cautious not to retaliate with a harsh tone even if attendants provoke them so that they may not have a chance to be uncooperative later specially for paying bills.

In this way doctor and medical team should be able to overcome this difficult situation of sudden death.

If the situation gets out of control and there is impending threat of mob violence or violence has been started, following measures have to be taken

1. Doctor and staff members should remain calm, should not get provoked.
2. One or two members should be assigned to take photographs or audiovisuals.
3. Records to be taken in custody.
4. Lawyer and Police to be informed.
5. Colleagues, friends and association members should be informed.
6. Doctor should not talk to everyone in the mob, few members from the mob should be allowed to talk separate from the mob, it is very essential to avoid any manhandling of doctor by mob as a result of unexpected hot talk.

7. Doctor should narrate to police in doctor's chamber preferably whole sequence of event properly in presence of colleagues and few sensible attendants of the patient.
8. In case if violence had been there, FIR should be lodged under Medicare Protection Act.
9. Doctor or hospital should not settle the issue by paying money. It has many undesirable consequences. It sends a message in society that somewhere doctor was at fault, that is why money was paid. It sends a wrong message that in case of death of the patient if violence is there, attendants shall get compensation then and there instead of going through tedious process of litigation.
10. Certify cause of death only if cause of death is identifiable.
11. Always insist on postmortem when cause of death is not identifiable or postmortem is indicated.

SUDDEN DEATH IN OPD

In case of OPD sequence of events shall be same but certain added precautions should be kept in mind.

It is advisable that when any patient comes for consultation in OPD his/her vitals should be recorded by one of the staff assigned for this purpose, any alarming finding in various parameters of temperature, blood pressure, respiration, heart rate and regularity should be communicated to the doctor for any immediate attention.

If a doctor is following a system of appointment for OPD patients, it is advisable to maintain compliance of time slot schedule as if some adverse event happens to a patient who is waiting for his/her turn and has not been taken care of as per allotted time slot, the doctor may be held liable for deficiency in service and as decided by supreme court in a case it may tantamount to medical negligence.

Medicolegal Aspects of Sudden Death

Sudden death in following situations needs to be informed to police:

- Sudden death on operation table or of postoperative patient.
- Sudden death from anaphylaxis due to a drug.
- Sudden death due to Stevens-Johnson syndrome.
- Sudden death of an admitted child who has fallen from bed or in bathroom.
- Sudden death after a procedure, for example after, liver biopsy and other biopsies, pleural fluid tapping, etc.
- Sudden death due to internal or external bleeding and disseminated intravascular coagulation.
- Sudden death during or postanesthesia.

In case of sudden death a doctor can face legal problem in two situations.

1. **A case of criminal negligence may be filed against the doctor:** In case of sudden death as in other cases also fortunately honorable supreme court of India has made it very difficult to hold a doctor criminally liable mainly by judgements in cases of Dr Suresh Gupta vs Delhi NCT and Jacob Mathew vs state of Punjab. To hold a doctor criminally liable a very high degree of negligence labeled as gross negligence is required. Supreme court has said in judgement in case of Jacob

Mathews vs state of Punjab that for establishing criminal medical negligence section 304A of IPC should be seen in the light of gross negligence, recklessness, total apathy towards the patient and mens rea.

2. In case of mob violence if it ensues after sudden death, a case under Section 304A of IPC can be filed against the doctor after due process of the opinion of medical board as per guidelines of supreme court.
   In some instances case under Section 304 of IPC has also been filed against the doctor stating a circumstantial evidence by the police in this regard.
   If doctor is arrested after due process under Section 304A of IPC, it is a bailable offence and bail can be granted from police station itself. In case of Section 304 of IPC doctor has to get bail from court.

Honorable Supreme Court in its judgment directed the central/state governments to frame statutory rules and executive instructions in regard to prosecution of doctors. (Jacob Mathews vs State of Punjab delivered on 5th August 2005). Until governments prepare such statutory rules, the honourable Supreme Court has given guidelines which should govern the prosecution of doctors for offences of which criminal rashness or criminal negligence is an ingredient. These guidelines are to be followed only when the death has occurred during the course of treatment. Whenever there is imminent arrest one can use copy of this judgment and ask the police officer to abide by the guidelines and a copy of the Act of violence against doctors in states where such an Act is in force should be shown to the police officer.

Places where Complaint Against the Doctor can be Filed

1. Consumer court for compensation.
2. Civil court for compensation.
3. Lok adalat.
4. Criminal court.
5. Medical Council for cancellation of registration.
6. Human Rights Commission.
7. Ministry of Health.
8. Authorities of CEA where in force.

REFERENCES

1. G Kumthekar. Sudden death, Textbook on medicolegal issues, 2012; 101–102.
2. Suresh Gupta vs Govt of NCT of Delhi (2004)6 SCC422.
3. Jacob Mathews vs. state of Punjab, AIR 2005 SC 3180.
4. Ratanlal and Dheerajlal. The Indian Penal Code, Chapter XV, 546–547.

Chapter
19

Violent Mob, Uncooperative, Aggressive Patient or Relative

Anurag Tomar

Although violence against doctors and other health workers is not uncommon, the incidence in India seems to be increasing. As there are certain responsibilities of doctors and other health care workers, similarly, responsibilities also have to be borne by patients and their relatives, political parties, hospital authorities, law maintaining machinery, media and government to see that health care improves and violence against doctors is strongly dealt with.

Indian Medical Association (IMA) reports that 75% of doctors in India have faced violence at some point of time in their life, with 12% of such violence occurring in the form of physical attacks and most of the time, it is verbal abuse. Emergency and ICU are the most violent venues and visiting hours are the most violent time. Escorts of patients have committed nearly 70% of such violence. Nearly 50% of such violence has been reported from intensive care units (ICU) or post-surgery. Peak hours and the transfer of critical patients to other hospitals are most susceptible to violence.

"Doctors can guarantee best treatment, but doctors cannot guarantee 100% results."To become a doctor is not easy. Doctor has to sacrifice his sleep—the time he/she spends caring for patients he barely knows; to sacrifice his/her youth—the time spend with books; sacrifice his family—the time spent away from home for education. But a doctor lives like an ordinary citizen. He does not demand subsidized groceries. He pays his electricity bills and phone bills. He buys all services at market rates.

ANCIENT CULTURE OF DOCTOR–PATIENT RELATIONSHIP

Doctors are called as God. From ancient time, in India, it is said that doctor comes at second position after God. It means that there is more responsibility of doctors towards patient. In illness, people either remember the doctor or the God. The bond between the doctor and patient depends upon both sides. There exists mutual relationship. The doctor–patient relationship is remarkable for its centrality during life-threatening and meaningful times in persons' lives, times of birth, death, severe illness, and healing. When this relation breaks from either side, the adverse situations arise.

IMPACT OF GLOBALIZATION ON DOCTOR–PATIENT RELATIONSHIP

Over the past two decades, the Indian subcontinent has witnessed an economic growth. With the rise of corporate hospitals, the mentality of physicians has changed from a

charitable to a lucrative one. Though not necessarily deleterious, this change has drastically influenced people's perception of physicians. Earlier even when there used to be one medical officer for an entire village or a small district, people's trust in the doctor remained high. The doctor was regarded as part of the local community and played integral role for the health and well-being of the social unit. With commercialization of health, more and more physicians have migrated toward corporate settings in urban centers, where large number of patients feel like a fish out of water.

The competition to enroll patients is often characterized by a combination of exaggerated promises and efforts to deliver less. Patients may arrive at the doctor's office expecting all their needs to be met in the way they themselves expect and define. They discover instead that the employer's negotiator defines their needs and the managed care company has communicated them in very fine or incomprehensible print. Primary care doctors thus become the bearers of the bad news, and are seen as closing gates to the patient's wishes and needs. When this happens, an immediate and enduring barrier to a trust-based patient–doctor relationship is created.

The doctor–patient relationship is critical for vulnerable patients as they experience a heightened reliance on the physician's competence, skills, and good will. Thus, providing health care, and being a doctor, is a moral enterprise. An incompetent doctor is judged not merely to be a poor businessperson, but also morally blameworthy, as having not lived up to the expectations of patients, and having violated the trust that is an essential and moral feature of the doctor–patient relationship.

VIOLENCE AND AGGRESSION DEFINED

Violence as defined in the *world report on violence and health* (WRVH), namely: "The intentional use of physical force or power, threatened or actual, against oneself, another person, or against a group or community, that either results in or has a high likelihood of resulting in injury, death, psychological harm, mal-development, or deprivation."

REASONS OF VIOLENCE AND AGGRESSION

Lack of adequate economic investment in health care is the main reason for violence. The government fund for health care infrastructure is not sufficient that results ill functional health care services. Small and medium private health care establishments, which provide a big share of health care services, are isolated and disorganized.[1] All these factors cause dissatisfaction among the public, and they take on their frustration onto doctors. The other factors attributed to violence against doctors are: Absence of postgraduate training in emergency medicine in India, poor quality of emergency care, poor mechanism for grievance readressal, poor emergency network among hospitals, poor communication skills of health care workers, resource and poor emergency.

Poor Image of Doctors and the Role of the Media

In India, doctors have traditionally been regarded highly by society. The present impression of private business-mindedness of some in the profession has led to a poor image of doctors. One of the factors that contributes to this poor image of doctors is the sensationalisation of every news item, often ignoring information that is true and

blaming a doctor in an incident of alleged medical negligence, this kind of journalism sells a negative image of the medical community. Such false negative image has sowed seeds of distrust in the minds of the people. As a hypothetical example, a television reporter shouting at the medical superintendent of a Delhi hospital reeling under a load of dengue patients as to why antimalarials were not given to a patient who died of dengue. This is done with an air of 'knowledge' that viewers would be convinced that not giving antimalarials to a patient of dengue in shock was medical negligence of the highest order.

Poor Quality Health Care

Government hospitals in India follow the welfare model, as majority of people are poor and do not have health insurance. Such hospitals offering subsidized medical care are swamped with patients and their attendants. The average medical officer posted in the outpatient department, sees close to 350 patients a day. It is logical to assume that quality of care gets sometimes compromised while attending to such a huge number of patients in a small window of time. This may impart a perception of neglect to the patient and leave him/her only partially satisfied. After waiting in long lines for hours, some patient's attendants are already at the brink of an emotional cliff. Ineffective communication or delay in attending to a patient can easily drive them over the edge. Since most patients lack health insurance, sometimes the diagnosis comes as a financial disaster and shocks them into emotional turmoil. This results in displacement of anger toward the physician.

Patients spent long time in waiting to meet doctors, multiple visits to get investigations done as well as consult doctors, sharing a bed by two and sometimes three patients and poor hygiene and sanitation. Due to these reasons, several times patients or their relatives lost their patience and becomes violent. There is frustration with systemic problems of government hospitals, from dysfunctional equipment to shortage of staff. Given the poor budgetary allocation for health in India, these problems are unlikely to change. Indian government's share in the health care delivery market is only 20%. The remaining health care providers are in the private sector. The private health care providers consist of private practitioners, for-profit hospitals and nursing homes, and charitable hospitals. Many incidents of violence have occurred at the time of billing and with any decrease in the already pitiable budget for health the situation is likely to deteriorate further.

Lack of Faith in the Judicial Process

Another cause of violence against doctors in India is the lack of faith in the law and order machinery and the judiciary.[2] A person with a grievance does not trust the mechanisms of redressal provided by law. There is sometimes a perception that doctors being well connected will get away and hence there is a tendency to take the law into their own hands by resorting to violence. There is also a belief that the patient's attendants who assault doctors will go unpunished.

Mob Mentality

Mob mentality frequently leads into a violent crisis in hospitals. In India, emotional turmoil due to death of a loved one is sometimes used by local politicians as an opportunity to demonstrate their political relevance by doing violence at the clinical

establishment for their 2-minute of fame and news coverage. Unique to India, the unfortunate death of a patient is sometimes given religious and caste colour by some miscreants, especially if the doctor belongs to a different caste or religion than the patient. Some party leaders feel no shame in publicly defaming physicians. In fact, a common method of gaining political mileage and securing the vote of the local community, is marching in a government hospital with the patient, and publicly manhandling the doctor. More often than not in India, patients by themselves are not violence makers, but their relatives are. Sometimes unknown apparently sympathetic individuals, political leaders[3] and political parties take the law in their hand. Majority of the hospitals in India do not have good grievance addressal system in place. Legal procedure in India also takes inordinately long time.

India is not the only country facing violence against its medical practitioners; today this is a global phenomenon. In the USA, between 1980 and 1990, over 100 health care workers died as a result of violence.[4] Another survey conducted in 170 university hospitals revealed that 57% of all emergency room employees had been threatened with a weapon over a 5-year period before the survey.[5] A survey of 600 doctors in 2008 by the British Medical Association revealed that though one-third respondents had been a victim of verbal or physical attack in the past year, over half of them (52%) did not report the incident.[6] Chinese doctors are often victims of violence. In June 2010, a doctor and a nurse were fatally stabbed in Shandong province by the son of a patient who died of liver cancer 13 years ago. A pediatrician in Fujian province was injured after leaping out of a fifth-floor window to escape angry relatives of a newborn baby under his care who had died.[7] 70% of physicians and 90% of support staff working in a hospital emergency room in Israel reported violent acts, mostly verbal abuse.[8] Violence in Bangladesh has been reported to occur mostly in the hospital setting, but in the private health care setting as well.[9] In a study of 675 physicians in training in nine tertiary institutes across Pakistan, 76% reported verbal or physical violence during the previous 2 months.[10] Another study from Pakistan by Imran et al reported that 74% of respondents in a public sector health care facility in Lahore were victims of violence during the preceding 12 months.[11]

According to a study by the Indian Medical Association, over 75% of doctors have faced violence at work.[12] A lady doctor in Tuticorin was killed by the husband of a pregnant woman who was admitted in a serious condition. She was referred to another hospital but died before she could be shifted. The husband entered the consultation chamber of the lady doctor with three accomplices and attacked her with a sword.[13] In 2014, in Mansa district of Punjab a doctor's clinic was burnt following death of a boy who was referred to a tertiary hospital but died.[14]

Innumerable incidents of violence against doctors are reported nearly on a daily basis across India, some resulting in grievous injuries. Even institutions such as the All India Institute of Medical Sciences, New Delhi, the premier medical institute of the country is not spared.

Low Health Literacy

This is often used to propagate myths and false accusations are made even in cases of death due to a previous illness. During emotional breakdown following death of near and dear ones, it becomes impossible to present or understand a rational view. In India, where 30–40% of cases of acute coronary syndromes present to emergency with

complaints of dyspepsia/gas,[15] it is difficult, if not impossible, to explain death during primary angioplasty due to ventricular arrhythmia. Unrealistic expectations are also part of the low health literacy. There is an increasing expectation of patients that with modern medicine and technology a doctor should be able to guarantee a good outcome.

Cost of Health Care

The rising cost of health care is the key reason for the breakdown of the bond between doctors and their patients. Even in the USA, catastrophic medical expenses account for half of all personal bankruptcies.[16] Physicians receive only 20% of all money spent on personal health care in the USA, but their decisions determine most of the remaining expenses. Even though the costs of all medical procedures in India are many times lower than those in Western countries, they are sufficiently high to cause many families to go into debt and slip below the poverty line. In a family where a regular meal takes primacy over health, anger and grief at losing someone despite spending beyond their means is understandable, but unfortunately it often culminates in violence. Whatever the provocation, justifying any violence especially against a doctor who tries to help in times of need has to be strongly condemned.

Poor Communication

One of the prominent reasons for patient–doctor mistrust is the perception of injustice within the medical sphere, related to profit mongering, knowledge imbalance and physician's conflict of interest. Patient–doctor mistrust precipitated medical disputes leading to outcomes such as nonresolution with patient resentment towards physicians or violent resolution such as physical and verbal attacks against physicians. Policy responses to violence included increased hospital security forces, which inadvertently fuelled mistrust. Instead of encouraging communication that facilitated resolution, medical disputes sometimes ignited a vicious cycle leading to mob violence.[17] Poor communication too is an important cause of rising incidents of violence in India. This is an area where much emphasis needs to be laid especially during medical training. Doctors are taught clinical behaviour but not empathy. Effective patient–doctor communication has been shown to correlate with patient satisfaction with health care services.[18] Aspects of patient–doctor communication such as 'receiving an explanation for the occurrence of the symptom/sign, likely duration of treatment and the lack of unmet expectations' were found to be key predictors of patient satisfaction.[19] Caregivers must be trained in breaking bad news, empathizing and communicating with their patients.

Lack of Security

Violence is easily planned in Indian health care establishments partly because security staff in the government and private sectors is nonexistent due to lack of funds. With meagre budgets, not sufficient to hire enough doctors and nurses, it would be unrealistic to expect adequate security in Indian hospitals except in a few corporate hospitals.

Types of Violence

Violence against doctors in India comprises: (i) Telephonic threats; (ii) oral/verbal abuse; (iii) physical noninjurious/injurious (simple and grievous), (iv) murder, etc. Doctors facing violence have been known to go into depression, insomnia, stress,

post-trauma, fear and anxiety causing absenteeism[20] in the UK; a similar situation likely prevails in India.

MANAGEMENT OF VIOLENT MOB

By the Management

There is an urgent need to make health care facilities a safe environment. Only then can health care professionals be expected to work with devotion and dedication. Sensational media coverage of the death of a patient due to a doctor's alleged negligence has only served to work against the patient's own interest. Health care professionals are now reluctant to handle serious cases; hence many precious lives that could have been saved are being lost.[21]

By the Government

Any complaint filed by a patient or the relatives in any court of law, forum or commission, should be automatically in fructuous and cancelled *ab initio* if proof of violence by the patients or the relatives can be provided by the hospital/doctor. This single change will stop all violence by the patient's attendants. This should be in addition to the punishment for violence under the Prevention of Violence against Medicare Persons and Medicare Institutions Acts and relevant sections of the Indian Penal Code (IPC).

The problem with the present law is that after violence has occurred, the doctor files a police complaint and simultaneously the patient and relatives file a complaint for criminal negligence. Finally, after the hue and cry has died down and news is no longer worthy of front pages the medical association stalwarts who led the agitation against the violence suddenly realize there has been a compromise between the two parties. This results in no punishment to the perpetrators and hence no deterrence for next incidence of violence. If on providing proof of violence any complaint of alleged negligence by patient party could be declared void *ab initio* automatically this will act as a strong deterrent for future incidents of violence.

By the Doctors

Do not Overreach

Modern medicine is changing rapidly. Hence, it is inappropriate to attempt to treat and do procedures beyond the scope of one's training and infrastructure. This is fraught with allegations of negligence and consequently of violence. The cardinal principle to prevent violence against doctors in India would be: 'Do not overreach'. Remaining within one's capability and experience is important in today's environment.

Consent

Valid and informed consent is the second most important step in preventing violence. Despite the rush and low health literacy, consent should not be considered a formality. Detailed consent in the patients' own words and language with witnesses (preferable) is mandatory before any invasive procedure. The purpose of treatment/surgery/procedure, its prognosis, the commonly occurring life-threatening and non-life-threatening complications must be explained. The available alternatives, advantages/

disadvantages and the consequences of refusal by the patient of treatment should be explained and mentioned in the consent form. It is also important to do only the procedure for which consent has been taken and not any additional procedure, even if it is in the 'patient's interest' unless it is a life-saving additional procedure.

Documentation

Proper documentation of the patient's course in hospital may not prevent violence but is important once violence occurs and the police are called. The records are often seized by the police. The doctor(s) later find it difficult to defend themselves because during the emergency they focused on saving the patient and not on maintaining proper records. Even in single-doctor clinics and nursing homes it is imperative to inculcate the habit of documenting everything or ask the nurse to document while the doctor is busy resuscitating the patient.

Communication

Improving communication skills will prevent doctors from facing violence in the long run. Even though medical practitioners in their forties and fifties may have cultivated their own methods to communicate with patients, it is imperative that they keep up with the times and train in communication skills from experts as part of their continuing medical education. This should be mandatory for all doctors to practice medicine in India.

Be Alert

Only by being aware that violence against doctors is a growing problem in India, it is possible to be alert and vigilant. Doctors need to evaluate each situation for potential violence when they enter a room or begin to relate with a belligerent patient or relative. It is important to be vigilant throughout the encounter and not isolate oneself with a potentially violent person or group. It is advisable to always try to keep an open path for exiting. Do not let the potentially violent person stand between you and the door. Friends, staff members, colleagues should collect at the site of incident without being provocative.

It is advisable to look for indicators of violent behaviour such as staring and eye contact, tone and volume of voice, anxiety, mumbling and pacing (STAMP).[22]

- Staring is an important early indicator of potential violence. Nurses have felt that staring was used to intimidate them into prompter action—when they responded to this cue violence tended to be avoided.
- Lack of eye contact has been found to be an issue and was associated with anger and passive resistance. However, there can be cultural reasons for avoiding eye contact and it is important to be aware of this.
- Tone and volume of voice has been associated with violent episodes.
- Many people who attend the emergency department are anxious and nurses are aware of how stressful such a visit can be. They should intervene before anxiety reaches dangerous levels, but sometimes patient's anxiety does escalate to violence.
- When anxiety levels are raised by the disorientation associated with conditions such as mental illness, substance misuse, dementia, epilepsy, diabetes and head injuries, this becomes an issue.

- A majority of patients who become violent have been observed to be mumbling, using slurred or incoherent speech or repeatedly asking the same question or making the same statements. Mumbling has been perceived to be a sign of mounting frustration and a cue for violence.
- Pacing was seen as an indication of mounting agitation and has been observed in instances that resulted in violence. Other physical indicators include staggering, waving arms or pulling away from health care personnel attempting to treat them.

Restrict Entry

The most important step in preventing mob violence in a hospital is restricting entry of the public. A large number of relatives should not be allowed at the patient's bedside. Entry should be strictly by visitor passes and this must be checked through security. Security must be placed inside the hospital at sensitive places as such as ICUs, operation theatres and casualty.

Standard Operating Procedure (SOP)

All clinical establishments should develop an SOP for violence. Mock drills need to be conducted and each member of the staff should be informed about his role if the situation of threatening or actual violence arise.

Insurance

Insure the establishment against mob violence, damage to property and injury to workers to at least mitigate the financial losses that are incurred in the aftermath of violence. If violence occurs:

1. Do not meet anger with anger. Remain calm in the face of provocation and let things blow over.
2. Depute someone (preferably beforehand) to take photographs and, even, audio/video records of the violence.
3. Depute someone to immediately (preferably as part of the SOP) get the medical record of the patient photocopied. If the mob carries away the original record, the photocopies will be useful.
4. Inform your lawyer.
5. Inform the police immediately by phone, etc. and keep a record of such phone call, etc.
6. Identify the troublemakers/leaders in the mob.
7. Get written, signed statements from the persons present (doctors, staff, patients, relatives, others) regarding the occurrence of violence.
8. Lodge an FIR with the police.
9. When making a police complaint the doctor/hospital should make sure that a request is made to register an FIR under the relevant Act for protection of medical personnel.

By the Operation of Law

Article 19(1)(b) of the Constitution gives the citizen the right to assembly subject to some conditions:

The assembly should be peaceful and without arms. The state can put reasonable restrictions on assembly in the interest of the nation's sovereignty, integrity or public

order. If the assembly continues despite legal prohibitions, it becomes unlawful and if its members use force or violence, it becomes civil disturbance.

The magistrates or authorized police officers can use Section 144 of CrPC, temporarily prohibiting persons from doing certain acts, even if they are perfectly lawful, such as carrying dangerous weapons, uttering slogans, restricting the use of roads or areas and imposing a curfew. In the exercise of powers conferred by Section 20 of CrPC, the state government can transfer these powers to civil police. The Indian Police Act has provisions that can even penalize localities that indulge in wanton violence.

LAW RELATING TO VIOLENCE AGAINST DOCTORS IN INDIA

Medical Protection Act

The protection of medicare service persons and medicare service institutions (Prevention of Violence and Damage to Property) Act, also known as the Medical Protection Act (MPA), has been passed by 19 states. As per this Act, any damage or Act of violence against medical professionals or their property is an Act punishable by imprisonment to for a minimum period of 3 years and fine amounting to Rs 50,000.

The stringent provisions of the Act not withstanding; it has failed to protect doctors in reality, because it features neither in the Indian Penal Code (IPC) nor in the code of criminal procedure (CrPC). This makes it difficult for victims to approach the police for help or for the latter to file a complaint against suspects.

Prevention of Violence against Doctors, Medical Professionals and Medical Institutions Act, 2019

- Any Act of violence against a doctor, medical professional or medical institution shall be prohibited and mitigated at all levels.
- Any offence committed under this Act shall be cognizable and non-bailable and triable by the Court of Judicial Magistrate of the First Class.
- Whoever, commits or attempts to commit or abets or incites the commission of any Act of violence in infringement of the provisions of Section 3, shall be punished with imprisonment which shall not be but which may extend up to five years and with fine which shall not be less than Rs 5,000 but which may extend up to Rs 5,00,000 in addendum to recovery of the entire damage to the property or belonging of all concerned including the witnesses if any; in actual.
- If the accused does not pay or is financially incompetent to pay the penalty at that time it shall be recovered as if it were an arrear of land revenue and any property belonging to his immediate relatives (as per the existing provisions of the Indian Penal Code 1860), may be attached in recovery of the said penalty.

STEPS NEEDED TO BE TAKEN

So, it is the foremost duty of state should commit to the safety and security of medical professionals. Although it is the immense responsibility of patients and their relatives and society at large to prevent violence. If there is any dispute between them it needs to be sorted but not through violence, there should be awareness about dispute

redressal which should be used and government needs to put the effort to prevent overcrowding in the hospitals. The government should take speedy action to punish unlawful behaviors of anybody who harms the doctors by implementation of the law.

Several ways for preventing violence to doctors are modification in the curriculum of study, developing communication skills, understanding patients who could be violent, being cautious at violent places, getting ready to run from the scene if need arises, educating patients and relatives, improvement in healthcare, etc.[23]

CONCLUSION

Doctors are also human being. The incidents of violence against doctors indicate that society is going to be handicapped. For the medical practitioners, it is important to be aware and be ready to handle situations. We hope that no more health care personnel lose their lives to violence after Medical Protection Act.

Though the current scenario seems gloomy, tackling the problem requires physician participation. Doctors should work with the government in creating an effective strategy to prevent hospital violence. Security personnel should be posted at the entrance of every hospital and should not let anyone through without checking for appropriate identification. Weapons should be confiscated before allowing passage to anyone. All attendants must register at the front desk and be given a visitor badge to be worn at all times. No more than two attendants should be allowed with the patient. Laws against doctor assault should be displayed on the walls. To ensure doctor safety, every hospital should create an emergency protocol and an evacuation plan in case of a major Act of violence.

The importance of teaching empathy to budding doctors cannot be stressed enough. Proper and effective communication with the patient and the attendants is an art, and should be taught to all young doctors. William Osler famously said, ***"The good physician treats the disease; the great physician treats the patient who has the disease"***.

In emergency and ICU settings, doctors should take time to clearly explain patient prognosis to attendants who may harbor unreasonable expectations. Counselors for emotional support should be available. Language translators can help in reducing chances of miscommunication. Since India is a Republic, The Rule of Law should prevail. Law should be enacted to safeguard the safety of doctors and nurses. Assaulting medical personnel on duty should be made a cognizable offense, with serious consequences. The media is the window of society. Demonizing physicians should be avoided and convicting doctors should be left for the courts.

Violence in any form and in any setting is condemnable. However, acts of violence in a hospital are the most extreme and should be dealt strictly. In addition to risking the safety of medical personnel, violence threatens patient safety and hampers their recovery to health. For the good of the Indian society, doctors rather than turning a cold shoulder, should work in tandem with the government as well as the public, to tide over this crucial problem.

Resident doctors and those who are practicing in rural areas are most at risk so more and more people are leaving the profession and stopping people from taking up this professionals. It is the foremost duty of state should commit to the safety and security of medical professionals.

REFERENCES

1. Nagpal, Neeraj. "Incidents of violence against doctors in India. Can these be prevented?" *The National Medical Journal of India* 2017; 30(2): 97–100.
2. Increasing cases of road rage: Why India so angry? NewsGram News Desk 15 April 2015.
3. Madhok P. Violence against doctors. *Bombay Hosp J* 2009; 51: 301–2.
4. Phillips JP. Workplace violence against health care workers in the United States. *N Engl J Med* 2016; 374: 1661–9.
5. Obama BH. Repealing the ACA without a replacement: The risks to American health care. *N Engl J Med* 2017; 376:297–9.
6. Goodman RA, Jenkins EL, Mercy JA. Workplace-related homicide among health care workers in the United States, 1980 through 1990. *JAMA* 1994; 272: 1686–8.
7. Anonymous. Chinese doctors are under threat. *Lancet* 2010; 376: 657.
8. Derazon H, Nissimian S, Yosefy C, Peled R, Hay E. Violence in the emergency department [Hebrew]. *Harefuah* 1999; 137: 95–101.
9. Assault and kidnap of a specialist doctor. The Daily *Kaler Kantho* 10 May 2010, Bengali.
10. Mirza NM, Amjad AI, Bhatti AB, tuz Zahra Mirza F, Shaikh KS, Kiani J, et al. Violence and abuse faced by junior physicians in the emergency department from patients and their caretakers: A nationwide study from Pakistan. *J Emerg Med* 2012; 42: 727–33.
11. Imran N, Pervez MH, Farooq R, Asghar AR. Aggression and violence towards medical doctors and nurses in a public health care facility in Lahore, Pakistan: A preliminary investigation. *Khyber Med Univ J* 2013; 5: 179–84.
12. Dey S. Over 75% of doctors have faced violence at work, study finds. Times of India, 4 May 2015.
13. Husband of dead patient kills doctor. The Hindu, 4 Jan 2012.
14. Boy dies during treatment, irate relatives ransack clinic, residence. Times of India, 15 May 2014.
15. Goold SD, Lipkin Jr M. The doctor–patient relationship: Challenges, opportunities, and strategies. *J Gen Intern Med* 1999; 14 (Suppl 1):S26–S33.
16. Himmelstein DU, Warren E, Thorne D, Woolhandler S. Illness and injury as contributors to bankruptcy. HealthAff (Millwood) 2005;Suppl Web Exclusives:W5- 63-W5–73.
17. Tucker JD, Cheng Y, Wong B, Gong Ni, Nie Jing-Bao, Zhu W, et al and the Patient–Physician Trust Project Team. Patient–Physician mistrust and violence against physicians in Guangdong Province, China: A qualitative study. *BMJ Open* 2015; 5.
18. Wong SYS, Lee A. Communication skills and doctor–patient relationship. Hong Kong Medical Diary 2006;II (3):7–8.
19. Jackson Jl, Chamberlin J, Kroenke K. Predictors of patient satisfaction. *Soc Sci Med* 2001; 52: 609–20.
20. Hobbs FD. Fear of aggression at work among general practitioners who have suffered a previous episode of aggression. *Br J Gen Pract* 1994; 44: 390–4.
21. Jawaid SA. Patient satisfaction, patient safety and increasing violence against healthcare professionals. *Pak J Med Sci* 2015; 31: 1–3.
22. STAMP system can help professionals to identify potentially violent individuals. Eurek Alert! The global source for science news. Washington, DC:Black Lack Publishing; 20 June 2007.
23. Smith M. Rise in violence against doctors in Turkey, elsewhere. *CMAJ*. 2015;187:643.

Chapter

20

Facing Electronic, Social and Print Media

Arun Kumar Agrawal, Rashmi Agrawal, ML Agnihotri, Abhinav Agrawal

Media is considered as one of the pillars of democracy. Traditionally media referred to as print media. However, in last two decades electronic and social media have taken grown exponentially. Nevertheless all three forms of media have a powerful impact in its area of influence. Hence, each one needs to be tackled appropriately.

It is a known fact that media has very big role in moulding the opinion of the society. Even before the case is settled in the court, the print and electronic media tend to conduct separate parallel investigation. It builds a public opinion against the doctor even before the court takes cognizance of the case. By this way it taints the public golden principle of presumption of innocence until proven guilty. Thus, media is not always fair and adds fuel to fire. Headlines like " death due to wrong injection", "death due to doctors carelessness", "late arrival of doctor leading to death" are often heard in the news. This powerful impact of media can be misused by patients and antisocial elements to their advantage.

Another form of media is social media. Social media has become widely used by individuals and businesses to stay connected, communicate and even market products or services.[1] As these sites evolve and become a prevalent way of reaching out to consumers, healthcare professionals are finding new, effective ways to utilize social media. Social media has become an integral part of many healthcare organizations' marketing and communications strategies. However, social media brings its own challenges. Here any user can act as a source of information. There is no need of any credentials to post a news nor is there any way to verify if a news is truthful or not. The wrong information which was posted either due to malicious intents or ignorance can go viral before it is corrected. Once it goes viral, it is available on thousands of websites. Now, it cannot be taken down even by the original author and remains as a source of online disrepute for doctor and hospital forever.

The big question is how to face the media. It is very difficult to reply to the media that is already biased. Still by being tactful, we cannot only tackle this problem but also use it to our advantage. There are certain principles to be followed:

- Face the media bravely and put your version.
- Reply only to the relevant queries but not to the irrelevant ones.
- Appoint only one sensible person to talk to the media. This will prevent multiple discordant versions of the same story. Also this way you can control what information you would like to let out.

- Say 'I prefer not to answer' to uncomfortable or irrelevant answers.
- Never lose your temper.
- Do not disclose all important facts which are relevant to the case. Keep some of the crucial ones for later use (example in court).
- Inform local body like IMA. If needed take their help for a press release with your version of the case.
- If you have an indemnity policy, never settle out of court. If you settle out of court it will encourage such antisocial people to take advantage of you again in future.

Handling a social media requires a slightly different strategy.[2]

- Determine the exact nature of the crisis (factual, rumour or malevolence).
- Go to the source. Find where the complaint originated and with whom. Determine their sphere of influence. If a social media user has published something that is untrue or misrepresentative of you, ask them to remove, amend, or modify the piece if this is appropriate.
- Be respectful, polite and engaged. or talk down to anyone. This is because being impolite quickly builds a negative opinion of you.
- Never get into a public argument.
- Be as transparent as possible as quickly as possible. Acknowledge that you are aware of the situation and that you are going to take appropriate measures after analysing the facts.
- Respond swiftly and appropriately. Every moment counts on social media. The longer you wait, the more the conversation will heat up. Once it is viral you may not be able to reverse the damage done.
- Do not lie or try to hide the truth; admit when the fault is yours in a tactful way. Say that the problem has come to your notice and you are investigating and will take appropriate measures as needed.
- Use the same channel on which you were criticized to respond.
- If possible censor or remove the critical comments that appear on your own social media platforms.
- Channel communication to your own website. Develop an area on your website or blog that houses the information about the crisis and what your organization is doing about it.
- Communicate your story. A story gets out of control when you have not told your side and people begin to speculate. While you cannot control the story, you can provide the facts, information, and access to key people that allow journalists and bloggers to help you frame it in the right way.

Once you have doused the fire and proved yourselves to be correct, do not relax. Try to take action (legal) against those who have wasted your valuable time, money and brought you disrepute. Certain indemnity policies cover this also. This way next time the local goons, antisocial elements will get a lesson and a message that they cannot harass you.

By following the steps mentioned in this chapter, you cannot only tackle the media but also used it to your advantage.

Skillful handling of media will go a long way to help to prove your innocence in the court of law.

REFERENCES

1. Ventola CL. Social media and health care professionals: benefits, risks, and best practices. PT. 2014;39(7):491–499.
2. https://hcsmmonitor.com/2019/05/16/a-three-stage-approach-to-handling-a-healthcare-social-media-crisis/. Accessed on 20th April. 2020.

Section

5

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Chapter

21

Visit by PCPNDT Team

Alka Kuthe

INTRODUCTION

The Prenatal Diagnostic Technique Act, 1994 and its subsequent amendments in 2003 as the Pre-conception and Prenatal Diagnostic (prohibition of sex selection) Act (PCPNDT Act) was brought into force to stop female feticide.

"It is no exaggeration to call this Gendercide. Women are missing in their millions-aborted, killed neglected to death."

The Economist Leaders: Gendercide. March 6th 2010

In order to curb the malpractices leading to declining of the child sex ratio and for better implementation of the Act, Amendments are added in Sections and Rules from time to time.

[The Prenatal Diagnostic Techniques (Regulation and Prevention of Misuse) Act 1994, Rules, 1996, Preconception and Prenatal Sex Selection and Diagnostic Techniques (prohibition of sex selection) Act, 2002, 2003. The Preconception and Prenatal Diagnostic Techniques (prohibition of sex selection) Amendment Act, 2012. The Preconception and Prenatal Diagnostic Techniques (prohibition of sex selection) (six months training) **Rules, 2014, Amendments Rules, 2017]**.

REGISTRATION OF THE CLINIC IS MANDATORY AS PER PCPNDT ACT

No person shall open any genetic counseling centre, genetic laboratory or genetic clinic, ultrasound clinic and imaging centre or scanner or any other technology capable of undertaking determination of sex of fetus and sex selection or render services to any of them unless such centre, laboratory or clinic is duly registered under this Act.

The state government shall appoint, by notification in the official gazette, one or more appropriate authorities for the whole or part of the state for the strict implementation of the Act, having regard to the intensity of the problem of pre-natal sex determination leading to female feticide. The state government shall also constitute an Advisory Committee to aid and advice the appropriate authority in the discharge of its functions, consisting of:

a. Three medical experts from amongst gynecologists, obstetricians, pediatricians and medical geneticists.
b. One legal expert.

c. One officer to represent the department dealing with information and publicity.
d. Three eminent social workers of whom not less than one shall be from amongst representatives of women's organizations.

VISIT BY PCPNDT TEAM

For ensuring strict compliance with the provisions of the PCPNDT Act, Section 30 gives full authority and power to an appropriate authority or any officer authorized by appropriate authority in this behalf, to enter and inspect a clinic, conduct search any premises at all reasonable times, with such assistance, if any, as such authority or officer considers necessary, such genetic counseling centre (GCC), genetic laboratory (GL), genetic clinic (GC), ultrasound clinic and imaging centre, where they have reason to believe that a breach of any of the provisions of the Act has been or being committed. Appropriate authorities are further authorized under the Act to seize and seal any record, register, document, book, pamphlet, advertisement or any other material object found therein if they have a reason to believe that it may furnish evidence of the commission of an offence punishable under the Act. As per Rule 12, appropriate authority or any officer authorized in this behalf can enter and search a clinic in the presence of two or more independent witnesses.

As per Rule 6(4) inspection of the premises of a USG clinic for grant/renewal of registration shall be carried out only after due notice is given to the applicant by the appropriate authority. The Act does not specify minimum space for USG room. But it should have sufficient space, to accommodate USG machine, its monitor and other attachments, examination table/cot for patient, doctor's chair and space for female attendant, without overcrowding. The doctor performing sonography should have necessary degree and the training as per the PCPNDT Act and the certificate should be kept preserved along with other records.

Every medical practitioner qualified under the Act to conduct sonography in a genetic clinic/ultrasound clinic/imaging centre shall be permitted to be registered with a maximum of two such clinics/centers within a district.

The consulting hours for such medical practitioner shall be clearly specified by each clinic/centre.

Whenever PCPNDT officer and the team authorized by appropriate authority visits GCC, GL, GC, ultrasound clinic and imaging centre, the team will note down the findings of inspection based on following points as per the provisions of PCPNDT Act and Amendment Sections and Rules.

PUBLIC INFORMATION

Display on Notice Board

Every genetic counseling centre, genetic laboratory, genetic clinic, ultrasound clinic and imaging centre shall prominently display on its premises a notice in English and in the local language or languages for the information of the public, to the effect that *"disclosure of the sex of the fetus is prohibited under law"*. (Antenatal sex determination is punishable offence and is not done here.) **[Rule 17(1)]**.

There is no specific size, shape, or color specified under the PCPNDT Act, but the board should be readable and should be displayed at a prominent place in the clinic and USG room.

Display of Registration of Certificate

Having regard to the advice of the Advisory Committee, the appropriate authority shall grant a certificate of registration in duplicate in Form B to the applicant. **[Rule 6(2)]** (Annexure 1, Form B.)

Only one registration per clinic is required (even if there is more than one machine). Details of all machines and all gynecologists (along with copies of their certificates) should be submitted. The details of machines (one or more) and the names of gynecologists are mentioned in the registration certificate or on a separate sheet by the appropriate authorities (AA).

The certificate shall be nontransferable and is valid for a period of **five** years from the date of its issue. One copy of certificate of registration shall be displayed by the registered GCC, GL or a GC, ultrasound clinic or imaging centre at a conspicuous place in the waiting room and another near the USG machine.

The appropriate authority may grant a certificate of registration to a genetic laboratory or a genetic clinic to conduct one or more specified prenatal diagnostic tests or procedures depending on the required criteria and standard maintained by such service providers.

Rule (2-A) (a) One copy of the certificate of registration shall be displayed by the registered mobile medical unit inside the vehicle at a conspicuous place.

For renewal of registration, the centre has to apply to appropriate authority thirty days before the date of expiry of the certificate of registration. Otherwise centre will be considered as unregistered and appropriate action will be taken under PCPNDT Act [Rule 8(1)].

Display Helpline Number and Website as follows in the Waiting Room

Report if disclosure of sex as prohibited under law and illegal termination of pregnancy on following:

- **Helpline No.: 18002334475**
- Website-www.amchimulgi.in
- *"Mulga mulgi ek saman, naka karu garbhaling nidan"*

PCPNDT Act Book Copy

At least one copy of each of the Act and Rules, 1996 shall be available on the premises of every GCC, GL, GC, ultrasound clinic and imaging centre **[Rule 17(2)]**.

A copy of the Act in English can be kept but it would be preferable to keep a copy of the Act in the local language and shall be made available to the client on demand for perusal.

Display of Name Plate

Name with designation prominently on the dress worn by him/her to avoid litigation like that of Ganganagar, Rajasthan [Rule 18(8)].

Machine Registration Certificate (MRC)

Machine identity number bearing sticker should be pasted on the machine. Machine registration certificate having machine identity number should be collected from the appropriate authority (Municipal Corporation/Civil Surgeon/DHO), signed and

displayed in the sonography room. Along with that owner should get machine identity number embossed/engraved on the metal part of the machine by the machine dealer.

Non-use of Machine

If the sonography machine is not working, it is for repairs, permanently not in use or is given back to company, the appropriate authority must be intimated. In case of permanent non-use of machine, it can be disposed off (demolished) in presence of appropriate authority or his representative.

VERIFICATION OF RECORDS BY INSPECTING AUTHORITY

What are the records to be maintained by a genetic counseling centre, genetic laboratory or genetic clinic?

Register

Every genetic counseling centre, genetic laboratory, genetic clinic including a mobile genetic clinic, USG and imaging centre shall maintain a register showing in serial order, the names and address of the men or women given genetic counseling, subjected to prenatal diagnostic procedures or prenatal diagnostic tests, the names of their spouse or father and the date on which they first reported for such counseling procedure or test **[Rule 9(1)]**.

Only obstetric USG entries should be made in the register in the format as below.

Sr. No.	*Name of men/women/given ultrasound clinic/genetic clinic/lab/counseling clinic*	*Address and contact No.*	*Subjected to pre-natal diagnostic procedure*	*Name of spouse/ father*	*Date on which they first reported*

A separate register may be maintained with name, address of the patients for USG examination performed other than obstetric USG.

Forms D, E, F, G

As per Rule 9(2), the record to be maintained by every genetic counseling centre in respect of each woman counseled shall be as specified in **Form D** (Annexure 2, Form D).

As per Rule 9(3), the record to be maintained by every genetic laboratory, in respect of each man or woman subjected to any prenatal diagnostic procedure/technique/test shall be as specified in **Form E** (Annexure 3, Form E).

As per Rule 9(4), the record to be maintained by every genetic clinic including a mobile genetic clinic, in respect of each man or woman subjected to any prenatal diagnostic procedure/technique/test shall be as specified in **Form F** (Annexure 4, Form F).

As per Rule 9(7), in case the genetic counseling centre, genetic laboratory or genetic clinic, ultrasound clinic or imaging centre maintain records on computer or other electronic equipment, a printed copy of the record shall be taken and preserved after authentication by a person responsible for such record. Thus, the hard copy of

Form F needs to be maintained even if it is being submitted online. Thus, the hard copy of Form F manually filled and a printout of the online submitted Form F need to be preserved. In both cases, it should have a declaration by the pregnant woman undergoing prenatal diagnostic procedure that she does not want to know the sex of the fetus and declaration by the doctor conducting the prenatal diagnostic procedure that he/she will not disclose sex of the fetus to anybody in any manner. The signature of both the client and doctor are mandatory on the hard copy. Printed copy taken online must be authenticated by the person responsible for such record.

As per the Act, there is no need to give a copy of Form F to the pregnant woman. However, if a pregnant woman demands a copy of the Form F, it can be given in addition to these forms.

Form G: Consent form for invasive procedures: As per Rule 10(1), before conducting pre-implantation genetic diagnosis or any prenatal diagnostic technique/test/procedure such as amniocentesis, chorionic villi biopsy, foetoscopy, foetal skin or organ biopsy or cordocentesis, a written consent, as specified in **Form G**, in a language the person undergoing such procedure understands, shall be obtained from her/him (Annexure 5, Form G).

Rule [(1-A)] Any person conducting ultrasonography/image scanning on a pregnant woman shall give a declaration on each report on ultrasonography/image scanning that she/he has neither detected nor disclosed the sex of foetus of the pregnant woman to anybody. The pregnant woman shall before undergoing ultrasonography/image scanning declare that she does not want to know sex of the foetus. It is mandatory for both patient and the person doing it, to sign the declaration form. Cases are filed against doctor on the ground that signature of patient on declaration form is not taken or doctor doing ultrasonography has not signed the declaration.

As per Rule 9(5), appropriate authority shall maintain a permanent record of applications for grant or renewal of certificate of registration as specified in **Form H**. Letters of intimation of every change of place, address and equipment installed shall also be preserved as permanent record. One has to give seven days advance notice to appropriate authority requesting to incorporate the changes and reissue the certificate. If there is delay on the part of the appropriate authority, it would not prevent the concerned clinic from effecting the changes and to continue with its activities. In so far as change in employees is concerned, instead of advanced notice such an intimation in written can be given within seven days of the change. There is no need to pay registration fee in case of change in place, equipment or person.

Referral Slip

Referral slip should be on the letterhead of the referring doctor and not on the letter head of the imaging centre. It should contain signature of the referring doctor (Annexure 6: Format for referral slip).

Self-referral Slip

Self-referral means a doctor's self prescription (if a doctor feels that a USG is indicated, such a note must be written on one's letter head). It does not mean a client coming to clinic and requesting for a test or relatives requesting for USG of a pregnant woman. (Annexure 6, format for self-referral slip).

Monthly Report

Every genetic counseling centre, genetic laboratory, genetic clinic, ultrasound clinic and imaging centre shall send a complete report in respect of all pre-conception or pregnancy related procedures/techniques/tests/conducted by them in respect of each month by 5th day of the following month to be concerned appropriate authority. **[Section 29, Rule 9(8)]** (Annexure 7: Monthly report format.) A copy of the same with the signature of the appropriate authority acknowledging receipt, must be preserved. Authorities insist on submitting 'NIL' report within a stipulated period of time, if there is no sonography during the respective month.

MAINTENANCE AND PRESERVATION OF RECORDS

Dual Advantage

- **From the point of view of the genetic counseling centre, genetic clinic, genetic laboratory,** if there is any complaint against them, the records will prove that they acted in accordance with the law.
- **From the point of view of the implementing authorities:** A doctor is bound to co-operate and produce records when asked by the appropriate authority and the Court and if he/she does not, adverse inference might be drawn. While non-maintenance of records can itself be a cause of action, the fact that proper records have been and have not been maintained can be indicative of the fact such hospitals are conducting prenatal diagnostic techniques for the purpose of determining the sex of the fetus.

For How Long are the Records to be Kept?

Section 29(2) of the Act states all records shall, at all reasonable times, be made available for inspection to the appropriate authority or to any other person authorized by the appropriate authority in this behalf.

Rule 9(6) states that all case related records, forms of consent, laboratory results, microscopic pictures, sonographic plates or slides, recommendations and letters shall be preserved by the genetic counseling centre, genetic laboratory or genetic clinic, ultrasound clinic or imaging centre for a period of **two years** from the date of completion of counseling, prenatal diagnostic procedure or prenatal diagnostic test as the case may be. In the event of any legal proceedings, the record shall be preserved till the final disposal of case or till the expiry of said period of two years, whichever is later.

Section 29(1) of the PCPNDT Act states that all records, charts, forms, reports, consent letters and all other documents required to be maintained under this Act and the Rules shall be preserved for a period of **two years** or for such period as may be prescribed. Provided that if any criminal or other proceedings are instituted against any genetic counseling centre, genetic laboratory or genetic clinic shall be preserved till the final disposal of such proceedings.

After the inspection by the appropriate authority, if there is reason to believe that the records may furnish evidence of the commission of an offence punishable under the Act, they may seize and seal the records (registers, documents, book, pamphlet, advertisement, any other material object). Also the appropriate authority has the power

to seize/seal the USG machine. Once the machine is sealed, it cannot be released during pendency of trial.

Can a Clinic Owner Demand for a Copy of the Inspection Report Carried out by Appropriate Authority?

As per Rule 18 A (8)(1) code of conduct for appropriate authority (amendment dated 24.2.2014), a copy of the inspection report should be given to the clinic owner.

The appropriate authority shall, after making such enquiry and after satisfying itself that the applicant has complied with all the requirements, place the application before the Advisory Committee for its advice [Rules 1996, 6(1)].

Having regard to advice of the Advisory Committee, the appropriate authority shall grant a certificate of registration, in duplicate, in Form B to the applicant [Rules 1996, 6(2)]. The certificate of registration shall be nontransferable. It will be valid for a period of **five** years from the date of its issue [Rule 1996(7)].

In case of renewal of registration, if appropriate authority shall, after holding an enquiry and after satisfying itself that the applicant complied with all the requirements of the Act and Rules, 1996 and having regard to the advice of the Advisory Committee in this behalf, renew the certificate of registration as specified in Form B, for a period of **five** years from the date of expiry of the certificate of registration earlier granted [Rule 1996 (2)].

In the event of failure of the appropriate authority to renew the certificate of registration or to communicate rejection of application for renewal of registration (Annexure 8, Form C) within a period of **ninety days** from the date of receipt of application for renewal of registration, the certificate of registration shall be deemed to have been renewed [Rule 1996 9(6)].

The appropriate authority can cancel or suspend registration either on its own or on a complaint received from anyone.

Following procedure is followed:

Show cause notice: On receipt of the complaint, the appropriate authority has to issue a show cause notice to the centre/laboratory/clinic.

Reasonable opportunity of being heard: It is given to the centre/laboratory/clinic allegedly contravening the Act.

Advisory Committee to be Consulted

Decision: To cancel or suspend registration will be taken by the appropriate authority after taking into account the advice of the Advisory Committee and giving chance of hearing to the centre.

Provision for Appeal

Rules 1996, Section 19:

1. Anybody aggrieved by the decision of the appropriate authority at sub-district level may appeal to the appropriate authority at district level within **30 days** of the order of the sub-district level appropriate authority.
2. Anybody aggrieved by the decision of the appropriate authority at district level may appeal to the appropriate authority at State/Union Territory level within **30 days** of the order of the district level appropriate authority.

3. Each appeal shall be disposed of by the district appropriate authority or by the State/Union Territory appropriate authority, as the case may be, within **60 days** of its receipt.
4. If an appeal is not made within the time as prescribed under sub-Rule (1), (2), or (3), the appropriate authority under that sub-Rule may condone the delay in case he/she is satisfied that appellant was prevented for sufficient cause from making such appeal.

Appeals against the order of the appropriate authority can be filed by the GCG/GC/GL within **30 days** of the order cancellation or suspension.

- With the central government if the order is passed by the central appropriate authority
- With the state government if the order is passed by the state appropriate authority.

CONCLUSION

Thus for ensuring strict implementation of the PCPNDT Act, the PCPNDT team/appropriate authority can use full authority and power while its visit to centre. Therefore to escape from the clutches of the Law, one must be fully aware of the requirements needed by the inspection team and co-operate without any fear in the mind.

For detail reading please refer:

www.ncpcr.govt.in PCPNDT Act, 1994
www.pndt.nic.in
Guide book for Genetic Counseling Centres/Genetic Clinics/Genetic Laboratories under PCPNDT Act, 2015.

Chapter
22

Issues Related to Termination of Pregnancy

Sudesh Doshi

INTRODUCTION

Medical termination of pregnancy has been an issue of ethical moral and religious dilemmas.

None of the religious texts approve of medical termination of pregnancy. Still medical termination of pregnancy (MTP) has been a necessity throughout ages. Illegal abortions are dangerous and often result in morbidity and mortality. Legal abortions are catered by trained people and at safe places with safe indications and hence have negligible morbidity and mortality.

Worldwide Scenario

About 26 countries do not permit medical termination on any grounds. It is available in rest of the world but the indications differ to a great extent.

Figure 22.1 depicts the legal status of abortion across countries, based on five broad categories.

Need for safe abortions was long felt by the community at large approximately 9% of maternal deaths are contributed by unsafe abortions which translate to about 3500 deaths per year.

Causes of Maternal Mortality in India

Policy makers in India realized this long ago and appointed Shantilal Shah Committee. On recommendations of this committee The Medical Termination of Pregnancy Act, 1971 (Act 34 of 1971) was passed by the parliament and came into force from 1st April 1972 to reduce the maternal mortality and morbidity associated with unsafe abortions.

It entitles women access to safe abortion services under certain specific conditions. The MTP Act lays down the criteria for which a pregnancy can be terminated, by whom, where and up to which gestational age. MTP is performed by qualified health providers using surgical methods or medical abortion drugs (mifepristone and misoprostol).

Only induced abortions come under the purview of the MTP Act, which therefore does not cover spontaneous, missed, inevitable and incomplete abortions.

The MTP Act offers protection to a practitioner if she/he adheres to the provisions of the MTP Act; and Rules and Regulations made under the MTP Act.

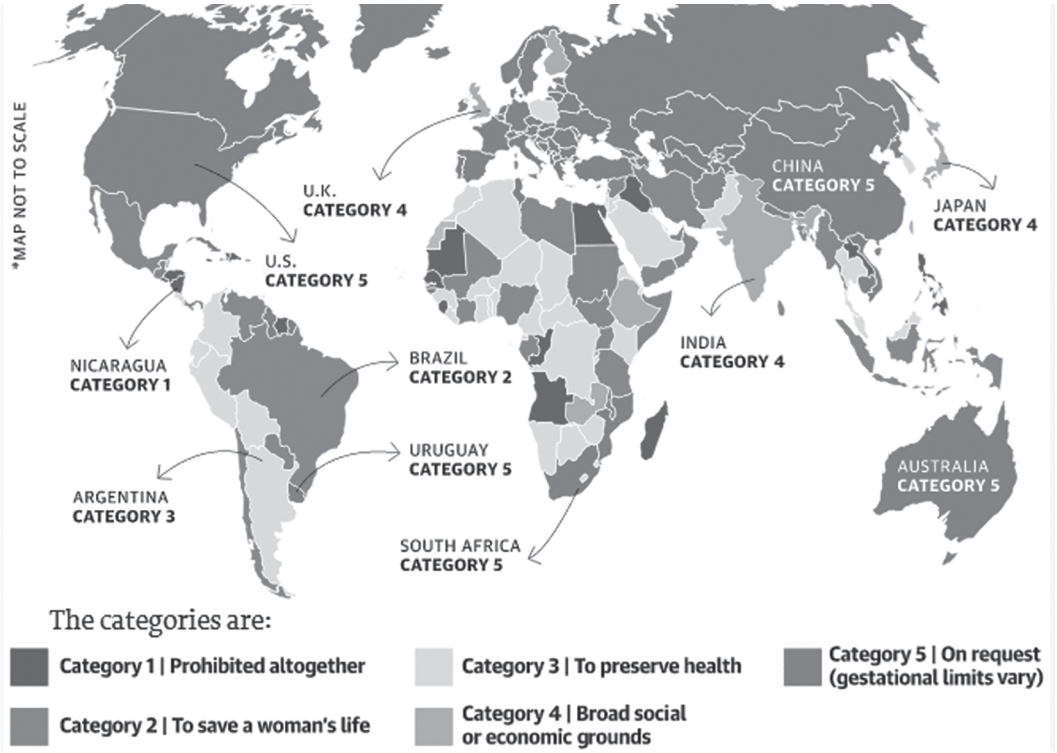


Fig. 22.1: Legal status of abortion across countries

The important Act, Amendments, Rules and Regulations governing MTP in India are:

1. **The Medical Termination of Pregnancy Act, 1971** (Act 34 of 1971)
2. MTP Act (Amendment), 2002
3. The Medical Termination of Pregnancy Rules, 2003.
4. The Medical Termination of Pregnancy Regulations, 2003.
5. The Medical Termination of Pregnancy (Amendment) Act, 2021.
6. The Medical Termination of Pregnacy Rules (Amendment), 2021

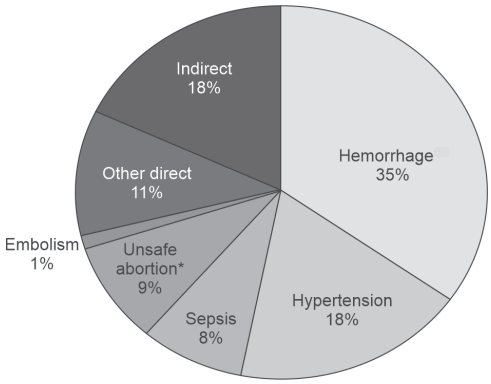


Fig. 22.2: Causes of maternal mortality in India

* Unsafe abortions

- The new law **will contribute towards ending preventable maternal mortality** to help meet the **Sustainable Development Goals (SDGs)** 3.1, 3.7 and 5.6. **SDG 3.1** pertains to **reducing maternal mortality ratio**, whereas **SDGs 3.7 and 5.6** pertain **to universal access to sexual and reproductive health and rights.**
- The amendments **will increase the ambit and access of women to safe abortion services** and will ensure dignity, autonomy, confidentiality and justice for women who need to terminate pregnancy.

The MTP Act and Rules were recently amended in 2021 to increase gestational age for termination up to 24 weeks.

The MTP Act provides details about the following aspects of abortion services:

1. Conditions under which pregnancy may be terminated. **[MTP Act: Section 3(2)]**
2. Who can provide abortion services. **[MTP Act: Section 2 (*d*) and Rule 4]**
3. Sites where abortion service can be provided. **[MTP Act: Section 4]**
4. Documentation and records for abortion services. **[Rule 5, Rule 9, Regulation 3, Regulation 4 (5), and Regulation 5]**
5. Punishments for violation of the MTP Act. **[MTP Act: Section 5 (2), Section 5 (3), and Section 5 (4)]**

Who can Provide MTP Sevices?

Currently, MTP can be legally provided only by a Registered Medical Practitioner (RMP)—a medical practitioner who possesses any recognised medical qualification as defined in Clause (h) of Section 2 of the Indian Medical Council Act, 1956, whose name has been entered in a State Medical Register and who has one or more of the following experience or training in gynecology and obstetrics **[MTP Act: Section 2(*d*); and Rule 4]**.

Rule 4

a. In the case of a medical practitioner, who was registered in a State Medical Register immediately before the commencement of the Act, experience in the practice of gynecology and obstetrics for a period not less than three years.
b. In the case of a medical practitioner, who was registered in a State Medical Register after the commencement of the Act and has completed six months of house surgency in gynecology and obstetrics or has experience at any hospital for a period of not less than one year in the practice of obstetrics and gynecology.
c. Has assisted an RMP in the performance of 25 cases of MTP of which at least five have been performed independently, in a hospital established or maintained by the government, or a training institute approved for this purpose by the government. *This training will enable the RMP to do only first trimester terminations (up to 12 weeks of gestation).*

   A registered medical practioner shall have following experience and training for conducting termination of pregnancy up to 9 weeks gestation period by medical methods of abortion only, namely (i) experience at any hospital for a period of not less than 3 months, three months in the practice of obstetrics and gynecology or (ii) has independently performed ten cases of pregnancy termination by using medical methods of abortion under the supervision of Registered Medical practitioner in hospital established or maintained, or a training institute approved for this purpose, by the government.
d. Holds a postgraduate degree or diploma in gynecology and obstetrics.

Legal Protection

Section 3(1) notwithstanding anything contained in the Indian Penal Code (45 of 1860), a Registered Medical Practitioner shall not be guilty of any offence under that Code or

under any other law for the time being in force, if any pregnancy is terminated by him in accordance with the provisions of this Act.

MTP Beyond 24 Weeks

3A. Powers and functions of Medical Board—for the purposes of Section 3:

a. The powers of the Medical Board shall be the following, namely:
   i. to allow or deny termination of pregnancy beyond twenty-four weeks of gestation period under sub-Section (2*b*) of the said section only after due consideration and ensuring that the procedure would be safe for the woman at that gestation age and whether the foetal malformation has substantial risk of it being incompatible with life or if the child is born it may suffer from such physical or mental abnormalities to be seriously handicapped;
   ii. co-opt other specialists in the Board and ask for any additional investigations if required, for deciding on the termination of pregnancy;

b. The functions of the Medical Board shall be the following, namely:
   i. to examine the woman and her reports, who may approach for medical termination of pregnancy under sub-Section (2*b*) of Section 3;
   ii. provide the opinion of Medical Board in Form D with regard to the termination of pregnancy or rejection of request for termination within three days of receiving the request for medical termination of pregnancy under sub-Section (2*b*) of Section 3;
   iii. to ensure that the termination procedure, when advised by the Medical Board, is carried out with all safety precautions along with appropriate counselling within five days of the receipt of the request for medical termination of pregnancy under sub-Section (2*b*) of Section 3.

Site Approval

1. A private site has to be approved by the District Level Committee (DLC) for providing MTP services. There are separate requirements for approval for up to 12 weeks, 12 to 24 weeks and beyond 24 weeks termination of pregnancy. **[MTP Act: Section 4 (*b*) and Rule 5]**
2. The certificate of approval by the DLC needs to be conspicuously displayed at the site to be easily visible to persons visiting the place. **[Rule 5 (7)]**
3. Public sector sites do not need separate approval for providing MTP services. **[MTP Act: Section 4 (*a*)]**
4. MTP Act allows provision of medical methods of abortion (MMA) up to nine weeks of pregnancy at an unapproved site provided it has access/referral linkages to an MTP approved site. For the purpose of access the RMP should display a certificate to this effect from the owner of the approved site. **(Rule 5 Explanation)**
5. MTP site approval does not need renewal unless the Chief Medical Officer (CMO), upon inspection, has a reason to believe that the facilities are not properly maintained and procedures are not conducted under safe and hygienic conditions, and the DLC suspends or cancels the site's approval. **[Rule 7 (1)]**

Record Keeping

Under the MTP Act (Table 22.1), the records that are **mandatory** for all facilities (government and private) are:

1. **Form I:** Opinion formed by RMP to provide services, is certified in this form. **[Regulation 3]** For length of pregnancy which does not exceed 20 weeks.
2. **Form C:** Consent for the termination of pregnancy is taken in this form. **[Rule 9]** Pregnancy of a woman who is above 18 years of age can be terminated with only her consent. If she is below 18 years of age or is mentally ill, written consent of guardian needs to be taken. **[MTP Act: Section 3 (4)]** ('Guardian' under the MTP Act means a person having the care of a minor or a mentally *ill person.)*
3. **Form D:** Opinion by the medical board for termination beyond 24 weeks.
4. **Form E:** Opinion form by two RMPs to provide services for termination from twenty weeks up to 24 weeks.
5. **Form III:** This is the Admission Register and is used to record details of women whose pregnancy is terminated. This needs to be kept for a period of five years from the end of the calendar year it relates to. **[Regulation 5]** Records pertaining to induced abortion/MTP services are confidential. They are not open for inspection by any person except under the authority of law. **[Regulation 6]**

Reporting

Form II: Monthly statement of MTP cases done at a hospital or approved place. The head of the hospital or owner of the approved place should send the monthly statement of MTP cases to the CMO of the district. **[Regulation 4 (5)]**

Table 22.1: Key provisions of MTP Act

Issue	*Key provisions*	*Additional information for implementation*
Conditions under which a pregnancy may be terminated	The MTP Act allows for termination of pregnancy on a broad range of conditions: • Continuation of the pregnancy would involve a risk to the life of the pregnant woman or it may cause grave injury to her physical or mental health • Substantial risk that the child, if born, would be seriously handicapped due to physical or mental abnormalities • Pregnancy is caused by rape (presumed to constitute grave injury to mental health) • Pregnancy is caused due to failure of contraceptive in woman or her partner presumed to constitute grave injury to mental health	Sex selection is not a legal ground for terminating a pregnancy. The provider/s must ensure that the ground for termination is clearly stated in the opinion form. The opinion of the provider is adequate to certify ground/s for providing abortion service
Place where a pregnancy may be terminated	Hospital established or maintained by the government or a place approved by the government or the District Level Committee (DLC) headed by the Chief Medical Officer (CMO) or District Health Officer (DHO). As per the National CAC guidelines, pregnancy may be terminated at government facilities up to: • Nine weeks of gestation at Primary Health Centre (PHC)	The CMO shall properly examine the application for approval before making a recommendation to the DLC for approving the place

(Contd.)

Issue	*Key provisions*	*Additional information for implementation*
	• 12 weeks of gestation at Community Health Centre (CHC) or 24 × 7 PHC • 24 weeks of gestation at District Hospital and above facilities. The DLC may approve a (private) place to conduct • Terminations up to 12 weeks • Terminations up to 24 weeks	
Who can terminate a pregnancy and who can form opinion	Medical termination of pregnancy can be legally provided only by a 'Registered Medical Practitioner' (RMP)—a medical practitioner who possesses any recognised medical qualification as defined in Clause (h) of Section 2 of the Indian Medical Council Act, 1956, whose name has been entered in a State Medical Register and who has one or more of the following experience or training in gynecology and obstetrics: Rule 4 a. In the case of a medical practitioner, who was registered in a State Medical Register immediately before the commencement of the Act, with experience in the practice of gynecology and obstetrics for a period not less than three years. b. In the case of a medical practitioner, who was registered in a State Medical Register after the commencement of the Act and: • Has completed six months of house surgency in gynecology and obstetrics • Has experience in any hospital for a period of not less than one year in the practice of obstetrics and gynecology c. Has assisted at RMP in the performance of 25 cases of MTP of which at least five have been performed independently, in a hospital established or maintained by the government or a training institute approved for this purpose by the government A registered medical practitioner shall have following experience and training for conducting termination of pregnancy up to 9 weeks gestation period by medical methods of abortion, namely: (i) experience at any hospital for a period of not less than 3 months in the practice of obstetrics and gynecology, or (ii) has independently performed ten cases of pregnancy termination by using medical methods of abortion under the supervision of a Registered Medical Practitioner in hospital established or maintained, or a training institute approved for this purpose, by the government d. Holds a postgraduate degree or diploma in gynecology and obstetrics	Up to 9 weeks by medical methods of abortion (a), (b), (c), (ca), (d) Up to 12 weeks by surgical method of abortion (a), (b), (c), (d) Up to 20 weeks (a), (b), (d) Beyond 20 weeks and up to 24 weeks opinion by two practitioners (a), (b), (d) termination by anyone (a), (b), (d) Beyond 24 weeks opinion by Medical Board Termination by two RMPs (a), (b), (d)
Certificate of approval	Form B: The certificate of approval for a 'private' place issued by the DLC chaired by the CMO shall be conspicuously displayed such that it is easily	The certificate of approval issued by the DLC chaired by the CMO is not for a

(Contd.)

Issue	*Key provisions*	*Additional information for implementation*
	visible to visitors. All Government facilities are by default approved to provide CAC services and therefore do not need a certificate of approval	fixed/limited period and does not require renewal. Doctors conducting MTP at the facility are not certified by the DLC. However, only an RMP as defined in the Act can perform MTP at an approved facility. Each district must have a functional DLC to ensure approval for private facilities and subsequent inspection of approved places. It is recommended for both public and private facilities to have site signages indicating availability of safe abortion services
Documentation	Form I: Opinion form for each MTP done must be duly filled with reason for termination and signature with date within three hours of termination of the pregnancy Form E: Opinion of the two RMPs in case of 20–24 weeks abortion must also be recorded either at the time of admission or within 3 hours of termination of pregnancy Form II: Reporting format: A monthly statement of all MTPs done must be sent to CMO on this format. This should include both surgical and medical methods of abortions (MMA). Form III: Admission register: All MTPs conducted at the facility must be recorded in the (confidential) admission register maintained at the facility for each calendar year	The column for indicating the reason for termination of the pregnancy must never be left blank. It must be filled as per the conditions prescribed in the MTP Act as relevant for the pregnant woman Incomplete abortion, inevitable abortion, missed abortion, blighted ovum are obstetric complications and do not come under the purview of the MTP Act and thus need not be recorded as per the MTP Act. The Admission Register is a confidential document and is not open to inspection by any person expect under the authority of law. The same has to be kept in safe custody. No entry of an MTP done shall be made in any case-sheet, operation-theatre register, follow-up card or any document or register other than the admission register maintained at the facility. Admission Register needs to be preserved for a period of 5 years from the date of last entry. There is no requirement for recording sex of the abortus in the Admission Register or any other records

(Contd.)

Issue	*Key provisions*	*Additional information for implementation*
Documentation	Form C: Consent Form: Consent of only the woman is required if she is of and above the age of 18 years. Only in case of a minor and/or a mentally ill woman of any age, her guardian's consent is required. Information about termination of pregnancy under the provisions of Section (5) of the MTP Act must be sent in a sealed envelope to the CMO the same day or the next working day	Consent from husband/parent/guardian is not required for seeking an abortion from a woman who is of or above 18 years of age and who is not mentally ill. Guardian under the MTP Act means a person having the care of a minor or a mentally ill person. This person does not necessarily have to be the legal guardian. Additional documentation of age proof is not required in addition to Form C
Medical methods of abortion (MMA) from unapproved facilities	In case of termination of early pregnancy up to 9 weeks using a combination of mifepristone with misoprostol, the RMP can prescribe the drugs at his/her clinic provided he/she has access to a place approved for terminating pregnancy under the Act	An RMP can prescribe MMA at a clinic that does not have the approval from the DLC only when he/she has displayed a certificate reflecting access to a certified place, issued by the owner of such place. MMA must be available in public health facilities as prescribed in the RMNCH + A framework
Inspection of Admission Register	The Admission Register is open to inspection only to a person under the authority of law	The confidentiality of the woman must always be ensured during inspection and should not be disclosed to anyone including media, etc.
Termination of pregnancy by an RMP at an unapproved place	In case of an emergency; any pregnancy may be terminated by an RMP to save the life of the woman at an unapproved place	Information about the same must be sent to the CMO the same day or latest by the next working day
Inspection of the approved place—taking suitable action	The CMO is authorised to inspect the places approved for conducting MTP to verify whether MTP is conducted under safe and hygienic conditions. The DLC, in appropriate cases, after affording opportunity to the owner, may suspend or cancel the certificate of approval. The owner may file a review application (within 60 days) to the government against such suspension or cancellation. The government, after giving the owner an opportunity of being heard may confirm, modify or reverse the order	The routine and periodic inspection by the CMO will ensure that safe and hygienic conditions are maintained for MTP service delivery. DLC members are not authorised to conduct inspections unless formally deputed by the CMO for the same

It is important to ensure that proper implementation of MTP Act at state and district levels such that safe abortion services are available to women.

Punishments under MTP Act

Section 5:

(2) Notwithstanding anything contained in the Indian Penal Code, the termination of pregnancy by a person who is not a Registered Medical Practitioner shall be an offence punishable with rigorous imprisonment for a term which shall not be less than two years but which may extend to "5A. (1) No Registered Medical Practitioner shall reveal the name and other particulars of a woman whose pregnancy has been terminated under this Act except to a person authorised by any law for the time being in force.

(2) Whoever contravenes the provisions of sub-Section (1) shall be punishable with imprisonment which may extend to one year, or with fine, or with both." Seven years under that Code, and that Code shall, to this extent, stand modified.

(3) Whoever terminates any pregnancy in a place other than that mentioned in Section 4, shall be punishable with rigorous imprisonment for a term which shall not be less than two years but which may extend to seven years.

(4) Any person being owner of a place which is not approved under Clause (b) of Section 4 shall be punishable with rigorous imprisonment for a term which shall not be less than two years but which may extend to seven years.

"5A. (1) No Registered Medical Practitioner shall reveal the name and other particulars of a woman whose pregnancy has been terminated under this Act except to a person authorised by any law for the time being in force.

(2) Whoever contravenes the provisions of sub-Section (1) shall be punishable with imprisonment which may extend to one year, or with fine, or with both.

ANNEXURES

Annexure I

FORM 1: For Termination up to 20 Weeks

SEE REGULATION (3)

I .....

(Name and qualifications of the Registered Medical Practitioner in block letters)

.....

.....

(Full address of the Registered Medical Practitioner) hereby certify that *I am of opinion, formed in good faith, that it is necessary to terminate the pregnancy of .....

.....

(Full name of pregnant woman in block letters) resident of .....

.....

.....

(Full name of pregnant woman in block letters)

for the reasons given below**.

* I/We hereby give intimation that *I/We terminated the pregnancy of the woman referred to above who bears the serial no. ..... in the Admission Register of the hospital/approved place.

Signature of the Registered Medical Practitioner

Place:

Date:

** of the reasons specified items (i) to (v) write the one which is appropriate.

i. in order to save the life of the pregnant woman,
ii. in order to prevent grave injury to the physical and mental health of the pregnant woman,
iii. in view of the substantial risk that if the child was born it would suffer from such physical or mental abnormalities as to be seriously handicapped,
iv. as the pregnancy is alleged by pregnant woman to have been caused by rape,
v. as the pregnancy has occurred as result of failure of any contraceptive device or methods used by married woman or her husband for the purpose of limiting the number of children.

Note: Account may be taken of the pregnant woman's actual or reasonably foreseeable environment in determining whether the continuance of her pregnancy would involve a grave injury to her physical or mental health.

Place:

Date: Signature of the Registered Medical Practitioner

Annexure II

Form E

Opinion Form of Registered Medical Practitioners

(For gestation age beyond 20 weeks till 24 weeks)

(See sub-Rule (2) of Rule 4A)

I .....

(Name and qualifications of the Registered Medical Practitioner in block letters)

.....

(Full address of the Registered Medical Practitioner)

I .....

(Name and qualifications of the Registered Medical Practitioner in block letters)

.....

(Full address of the Registered Medical Practitioner)

hereby certify that we are of opinion, formed in good faith, that it is necessary to terminate the pregnancy of

.....

(Full name of pregnant woman in block letters)

resident of .....

(Full address of pregnant woman in block letters)

which is beyond twenty weeks but till twenty-four weeks under special circumstances as given below*.

* Specify the circumstance(s) from (a) to (g) appropriate for termination of pregnancy beyond twenty weeks till twenty-four weeks:

(a) Survivors of sexual assault or rape or incest

(b) Minors

(c) Change of marital status during the ongoing pregnancy (widowhood and divorce)

(d) Women with physical disabilities [major disability as per criteria laid down under the Rights of Persons with Disabilities Act, 2016 (49 of 2016)]

(e) Mentally ill women including mental retardation

(f) The foetal malformation that has substantial risk of being incompatible with life or if the child is born it may suffer from such physical or mental abnormalities to be seriously handicapped

(g) Women with pregnancy in humanitarian settings or disaster or emergency situations as declared by government.

We hear by give intimation that we terminated the pregnancy of the woman referred to above who bears the Serial No. ..... in the Admission Register of the hospital/ approved place.

Signature of the Registered Medical Practitioner

Place:

Date:

Note: Account may be taken of the pregnant woman's actual or reasonably foreseeable environment in determining whether the continuance of her pregnancy would involve a grave injury to her physical or mental health.

Annexure III

Form C
(See Rule 9)

I ..... daughter/wife of .....
aged about .....years of .....
(here state the permanent address) at present residing at .....
.....
do hereby give my consent to the termination of my pregnancy at .....
..... (state the name of place where the pregnancy is to be terminated)

Place
Date Signature

(To be filled in by guardian where the woman is a mentally ill person or minor)

I .....son/daughter/wife of .....
aged about ..... years of .....
(permanent address) at present residing at .....
.....
do hereby give my consent to the termination of the pregnancy of my ward .....
.....
who is a minor/mentally ill person at .....
..... (place of termination of pregnancy)

Plate:
Date: Signature

Annexure IV

FORM III

(See Regulation 5)

ADMISSION REGISTER

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
(To be destroyed on the expiry of five years from the date of the last entry in the register	Date of admission	Name of patient	Wife/ Daughter of	Age	Religion	Address	Duration of pregnancy	Reasons on which pregnancy is terminated	Date of termination of pregnancy	Date of discharge of patient	Result and remarks	Name of Registered Medical Practitioner(s) by whom the opinion is formed	Name of Registered Medical Practitioner(s) by whom pregnancy is terminated	Method of MTP/MVA/ MMA/EVA/ others	Post abortion contraception TI/OC/CD/ Inj Tables/ Other

Annexure V

Form D

(See sub-Clause (ii) of Clause (b) of Rule 3A)

Report of the Medical Board for Pregnancy Termination Beyond 24 Weeks

Details of the woman seeking termination of pregnancy:

1. Name of the woman: .....
2. Age: .....
3. Registration/Case Number: .....
4. Available reports and investigations:

S. No.	Reports	Opinion on findings

5. Additional investigations (if done):

S. No.	Investigations done	Key findings

6. Opinion by Medical Board for termination of pregnancy:
   a. Allowed
   b. Denied

   Justification for the decision:
7. Physical fitness of the woman for the termination of pregnancy:
   a. Yes
   b. No

   Members of the Medical Board who reviewed the case:

S. No.	Name	Signature

S. No. ..... Name ..... Signature: .....
Date and Time:……

Annexure VI

Form A

(See sub-Rule (2) of Rule 5)

Form of Application for the Approval of a Place under Clause (b) of Section 4 of the Act

Category of approved place:

(A) Pregnancy can be terminated up to twelve weeks

(B) Pregnancy can be terminated up to twenty-four weeks

(i) Name of the place (in capital letters):

(ii) Address in full:

(iii) Non-Government or Private or Nursing Home or Other Institutions:

(iv) State, if the following facilities are available at the place:

CATEGORY A

(i) Gynecological examination or labour table.

(ii) Resuscitation equipment.

(iii) Sterilisation equipment.

(iv) Facilities for treatment of shock, including emergency drugs.

(v) Facilities for transportations, if required.

CATEGORY B

(i) An operation table and instruments for performing abdominal or gynecological surgery.

(ii) Drugs and parental fluids in sufficient supply for emergency cases.

(iii) Anesthetic equipment, resuscitation equipment and sterilization equipment.

Place:

Date: Signature of the owner for the place."

Annexure VII

Form II for Monthly Reporting

Form II refer Regulation 4[5]	Month and year	
1. **Name of the State**		
2. **Name of Hospital/Approved [place]**		
	Monthly	Progressive
3. **Duration of pregnancy [give total number only for each sub-head]**		
a. Up to 9 weeks [medical method of abortion only]		
b. Up to 12 weeks (surgical method of abortion only]		
c. Between 12 and 20 weeks		
d. Between 20 and 24 weeks		
4. **Religion of woman**		
a. Hindu		
b. Muslim		
c. Christian		
d. Others		
5. **Termination with acceptance of contraception**		
a. Sterilization		
b. IUCD		
c. OCP/injectable contraceptives		
d. Others		
6. **Reasons for termination**		
A. Up to 20 weeks of gestation		
a. Danger to life of pregnant woman		
b. Grave injury to physical and mental health of pregnant woman		
c. Pregnancy caused by rape		
d. Substantial risk that if the child was born it suffers from such physical and mental abnormalities as to be seriously handicapped		
e. Failure of any contraception device		
B. Between 20 and 24 weeks of gestation		
a. Survival of sexual assault/rape/incest		
b. Minors		
c. Change of marital status during the on-going pregnancy [widowhood and divorce]		
d. Women with physical disability		
e. Mentally ill women including mental retardation]		
f. The foetal malformation that has substantial risk of being incompatible with life or if the child is born it may suffer from such physical and mental abnormalities as to be seriously handicapped		
g. Women with pregnancy in humanitarian settings or disasters or emergency situation decided by government		
C. Beyoned 24 weeks of gestation		
The foetal malformation that has substantial risk of being incompatible with life or if the child is born it may suffer from such physical and mental abnormalities as to be seriously handicapped		

Signature of office in-charge with date

REFERENCES

1. Calculated estimates from RGI SRS 2001–03.
2. Medical Termination of Pregnancy Act, 1971.
3. The Medical Termination of Prgnancy Rules, 2003.
4. The Medical Termination of Pregnancy Regulations, 2003.
5. The 'CAC Training and Service Delivery Guidelines (2010)' by the Ministry of Health and Family Welfare.
6. Government of India offer recommendations for high quality abortion care services. (http://nrhm.gov.in/images/pdf/programmes/maternal-health/guidelines/abortion_care_training.pdf.

Chapter

23

Tubectomy Death: The Issues

Ragini Agrawal, Nidhi Yadav

INTRODUCTION

Tubectomy has been one of the best permanent method of sterilization for females in India to avoid unwanted and unintentional pregnancy once their family is complete with the failure rate of only 0.1%, i.e. 1/1000. Besides the failure of the tubectomy, one of the most serious complications can be death due to tubectomy procedure. Mortality following tubal sterilization is estimated to be 72 per 100,000 for all methods. Laparoscopic procedures carried the mortality rate of 5–10 per 100,000 compared to 7 per 100,000 for puerperal ligation.[1] India is the first country that launched a National Family Planning Programme in 1952, with the objective of reducing birth rates to the extent necessary to stabilize the population at a level (which is approximately 1,369.56 million inhabitants in 2020 in India) consistent with the social and economic development and environment protection.

CASE ILLUSTRATION

A female, whose family is complete, post-vaginal delivery of a 8-day-old male child without any postpartum complication and in healthy condition got admitted on 9th day in a hospital for tubectomy, died post-tubectomy operation. Patient was fit for surgery according to anesthetist and surgeon. After couple of hours patient complained of breathlessness gradually going into the shock condition. Emergency and supportive treatment was given to her but she could not survive. The cause, of death given by doctors was 'cardiorespiratory arrest'. Family of the deceased lodged a police complaint and requested medicolegal inquiry. Medicolegal postmortem was conducted.

After postmortem examination, the histopathological report and chemical analysis final cause of death was given as shock as a result of intra-abdominal hemorrhage due to, cut over right ovarian vessels.

Discussion: Major or minor complications of tubal ligation surgery are treatable by proper care, medication and repeat surgery. Patient care is a duty of doctor in minor/major operation to avoid life-threatening conditions. Operating person should keep reasonable care and skill in mind as a part of patient care during operation and post-operation. In the postoperative period, the patient should be closely monitored.

Some intraoperative complications which can lead to death of the patient if not managed promptly in emergency by OP are vasovagal attack, respiratory depression,

cardiac arrest, convulsions and toxic reactions to local anesthesia, gas embolism, uterine perforation (may occur due to introduction of uterine elevator from below), bleeding from the mesosalpinx during minilap procedure, injury to urinary bladder, injury to intra-abdominal viscera (i.e. small or large bowel) and blood vessels, subcutaneous emphysema, etc.

Few postoperative complications that can lead to death of the patient post-tubectomy are wound sepsis, hematoma in the abdominal wall, intestinal obstruction, paralytic ileus and peritonitis.

The question of criminal negligence may arise in a criminal court, when the complainant's counsel may attribute the death of an assaulted person to the negligence or undue interference of the medical attendant in the treatment of the deceased. For criminal negligence, the medical practitioner, whether qualified or unqualified, may be prosecuted by the police and charged in a criminal court with having caused the death of his patient by doing a rash or negligent Act which shows gross carelessness, or gross ignorance during administration of an anesthesia, performance of an operation or any other treatment.[2] Indian Penal Code (IPC) provides Section 304(*a*) for negligence under which doctors can be held liable for criminal negligence.

Operating person (OP) should rule out the possibility of shock or any other complication by proper examination, investigation or taking opinion from another experienced surgeon. During operation, ovarian vessels were cut by sharp cutting operative instrument and before closing the abdomen OP did not make any confirmation about any leaking vessels. All complications cannot be treated as doctor's negligence if due care is taken of patient during operation and after operation and if the complication occurs anyway then it is managed by the doctor with his maximum skills and capacity. In the present case, the gynecologist is liable for criminal negligence under Section 304(*a*) which is a punishable offence.

Conclusions of Illustration

1. A surgeon should be mindful of all the possibility of complications of surgery. If any complication arises preoperatively or postoperatively OP with all due care and skills should manage the patient in emergency or non-emergency situations arising out of such complication. Failing to do so, a OP can be held liable for criminal negligence.
2. Postmortem and other pathology reports would confirm such possibility of injury to organ or vessels while dealing with a case of death following tubectomy.

CASE LAWS

Rajmal vs state of Rajasthan, AIR 1996 Raj 80(Raj HC)[3]: Petitioner's wife while being operated for laparoscopic tubectomy on 2.4.1989 at primary health, Gangapur city, died—death caused by neurogenic shock resulting in cardiac arrest while cause of death rare, court directed for appointment of high level Enquiry Committee submitted its report on 15.7.1992 according to which operating doctor not found negligent in conducting operation, nor his competence, integrity or efforts were doubted. Lack of adequate resuscitative facilities and trained staff responsible for

death—state government held vicariously liable to pay compensation of Rs 1 lakh to husband of deceased—High Court further gave direction to the state government to provide trained staff to assist doctor and necessary medical equipment, e.g. endotracheal intubation equipment, defibrillator, cardiac monitor, etc. while conducting laparoscopic tubectomy operation.

Achutrao Haribhau Khodwa vs state of Maharashtra,1996 SC[4]: Two questions which arise for consideration in this appeal are whether the State of Maharashtra can be held liable for any negligence of its employees and secondly whether the respondents or any one of them acted negligently in the discharge of their duties.

Dr Divan and Dr Purandare have stated that the cause of death was peritonitis. In a case like this the doctrine of *res ipsa loquitur* clearly applies. Chandrikabai had a minor operation on 13th July, 1963 and due to the negligence of respondent no. 2 a mop (towel) was left inside her peritoneal cavity. It is true that in a number of cases when foreign bodies are left inside the body of a human being either deliberately, as in the case of orthopaedic operations, or accidentally but it also happens that complications can arise when the doctor acts without due care and caution and leaves a foreign body inside the patient after performing an operation and it suppurates. The formation of pus leaves no doubt that the mop left in the abdomen caused it, and it was the pus formation that caused all the subsequent difficulties. There is no escape from the conclusion that the negligence in leaving the mop in Chandrikabai's abdomen during the first operation led, ultimately, to her death. But for the fact that a mop was left inside the body, the second operation on 19th July, 1963 would not have taken place. It is the leaving of that mop inside the abdomen of Chandrikabai which led to the development of peritonitis leading to her death. She was admitted to the hospital, on 10th July, 1963 for a simple case of delivery followed by a sterilization operation. But even after a normal delivery she did not come out of the hospital alive.

Bansidhar Panigrahi vs Chief Medical Officer, Ganjam 1993[5]: In the instance of this case, a tubectomy operation was done on the patient and she left the hospital at her accord in spite of knowing that there are possibilities of complications after the operations. The state commission *held* that disease contributed to her death is not keeping the operation wound clean for which she got infection from her home as others who are operated on the same day were not affected by the disease and there was no negligence on the part of operating surgeon, paramedical person and in the treatment given at the hospital.

Rajmal vs State of Rajasthan and Anr. on 3 November, 1995[3]: Rajasthan high court *held* that while cardiac arrest due to pneumoperitoneal needle insertion is rare but not unknown, we feel that the life of the patient could have been saved if adequate resuscitative facilities, e.g. endotracheal intubation, defibrillator and cardiac monitoring equipment had been available. Since every human life is equal, we feel that whenever laparoscopic tubectomy is being done whether in a major hospital or in smaller hospital or in a laparoscopic tubectomy camp, a trained anesthetist with M.S. degree in anesthesiology, and the above mentioned equipment should be available. This should be mandatory for every laparoscopic tubectomy operation, in view of the sensitive nature of the operation and the fact that the patient is young, disease free and healthy.

Other than the lack of the above mentioned resuscitative equipment and trained anesthetist, we find no evidence to doubt the competence or integrity or efforts made by Dr C.P. Gupta.

IMPORTANCE OF FOLLOW-UP

1. The first follow-up contact should be within 48 hours of discharge.
2. The second follow-up visit should be after one week of surgery for detailed examination of patient.
3. Subsequent follow-ups can be scheduled after 1 month.
   During follow-ups any kind of complication should be noticed and examined. Such dissatisfaction or side-effects post-surgery should be taken seriously and also due diligence and prompt care should be given to the patient.
4. In case patient show up in emergency with any complication post-surgery, staff of the hospital should immediately inform OP and should immediately attend the patient. A complete thorough examination should be done. Medical history should be taken and medical records should be checked in details. All necessary treatment should be given to the patient to stabilize the patient and for treating the complication per se.

LEGAL PROVISIONS

Studies have shown higher rates of death and failure of procedure as a consequence of not following the government guidelines The Hon'ble Supreme Court of India in its order dated 1.3.2005 in Civil Writ Petition No. 209/2003 **(Ramakant Rai vs Union of India)** has, inter alia, directed the Union of India and States/UTs for enforcing standard guidelines for conducting sterilization procedures all over India by:

1. Creation of panel of doctors/health facilities for conducting sterilization procedures and laying down of criteria for empanelment of doctors for conducting sterilization procedures.
2. Laying down of checklist to be followed by every doctor before carrying out sterilization procedure.
3. Laying down of uniform performa for obtaining of consent of person undergoing sterilization.
4. Setting up of Quality Assurance Committee for ensuring enforcement of pre- and postoperative guidelines regarding sterilization procedures.
5. The state shall also bring into effect an Insurance Policy etc. until such time the Union of India prescribes a standard format.

A more supportive regulatory regime for victims of negligence in case of sterilisation operation is the Family Planning Insurance Scheme launched in 2005.

REVISED SCHEME (PART OF STATE PROGRAMME IMPLEMENTATION PLANS (PIPS) W.E.F. 1ST APRIL, 2013

This scheme being the 6th revised scheme since 2005, w.e.f. 01-04-13 to 31-3-2014, is a part of State Programme Implementation Plans (PIPs) under NRHM, and renamed as Family Planning Indemnity Scheme. The available benefits are as follows:

Section	*Coverage*	*Limits*
IA	Death following sterilization (inclusive of death during process of sterilization operation) in hospital or within 7 days from the date of discharge from the hospital	Rs 2 lakhs
IB	Death following sterilization within 8–30 days from the date of discharge from the hospital	Rs 50,000
I C	Failure of sterilization	Rs 30,000
I D	Cost of treatment in hospital and up to 60 days arising out of complication following sterilization operation (inclusive of complication during process of sterilization operation) from the date of discharge	Actual not exceeding Rs 25,000
II	Indemnity per doctor/health facilities but not more than 4 in a year	Up to Rs 2 lakhs per claim

Note: The details of the scheme is available in 'Manual for Family Planning Indemnity Scheme', available on http://nrhm.gov.in/nrhm-components/rmnch-a/family-planning/schemes.html

Eligible Beneficiaries/Doctors/Health Services Providers[7]

a. All persons undergoing sterilization operations and signed the Consent Form are covered under Section I(A), I(B), I(C) and I(D).
b. All the doctors/health facilities private, government or non-government empanelled/accredited with District Health Authority for rendering Family Planning Services and conducting such operations shall stand indemnified against the claims arising on them out of failure of sterilization, death or medical complication resulting there from up to a maximum amount of Rs 2 lakh per case, maximum up to 4 cases per doctor/health facility per year.

The cover would also include the legal costs and actual modality of defending the prosecuted doctor/health facility in court, which would be borne by the respective State/UTs within the limits of Section II.

Liability of the coverage by insurance company underneath this segment would be restrained to four cases per doctor per year for the negligence, beyond which the physician/health centre might be himself/herself responsible for his/her lapse, aside from some other action taken against the doctor or health facility by government.

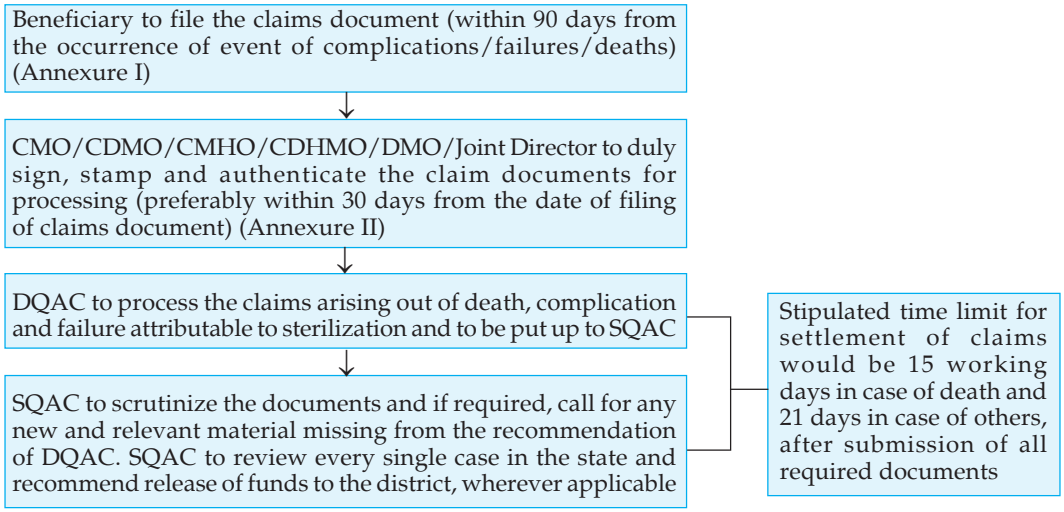
This became essential due to the fact medical doctors and facilities have been reluctant to perform sterilisation operations fearing litigation in case the technique failed. The scheme provides an important shield to ensure doctors participation in the sterilisation program, that is critical for the fulfilment of the population policy.

IMMEDIATE STEPS IF DEATH IS CAUSED (ANNEXURE I)

Annexure I shall be immediately filled up by beneficiary through their designated hospital and doctors for the claim under Section I.

If such covered cause is detected 'during examination of the accepter in health facility', the health facility shall ensure to get the claim Form filled from the beneficiary on the spot without loss of time. The health facility shall forward the claim papers along with necessary documents to the designated officer of the district.

Steps of the Claim Process[6]


Beneficiary to file the claims document (within 90 days from the occurrence of event of complications/failures/deaths) (Annexure I)
CMO/CDMO/CMHO/CDHMO/DMO/Joint Director to duly sign, stamp and authenticate the claim documents for processing (preferably within 30 days from the date of filing of claims document) (Annexure II)
DQAC to process the claims arising out of death, complication and failure attributable to sterilization and to be put up to SQAC
SQAC to scrutinize the documents and if required, call for any new and relevant material missing from the recommendation of DQAC. SQAC to review every single case in the state and recommend release of funds to the district, wherever applicable
Stipulated time limit for settlement of claims would be 15 working days in case of death and 21 days in case of others, after submission of all required documents

LEGAL DOCUMEMTS AND ESSENTIALS (ANNEXURE)

Requirement of Documents for Claim under Family Planning Indemnity Scheme

i. **Death following sterilization (Section I(*a*) and I(*b*):**

a. Claim Form (Annexure I)-cum-medical certificate in original duly signed and stamped by the CMO/CDMO/CHMO/CDHMO/DMO/DHO/Joint Director designated for this purpose at district level.

b. Copy of consent Form (Annexure III and V) duly attested by CMO/CDMO/ CHMO/ CDHMO/DMO/DHO/Joint Director designated for this purpose at district level.

c. Copy of sterilization certificate (Annexure IV and V) duly attested by CMO/ CDMO/ CHMO/CDHMO/DMO/DHO/Joint Director designated for this purpose at district level.

d. Copy of proof of postoperative procedure/discharge certificate duly attested by CMO/CDMO/ CHMO/CDHMO/DMO/DHO/Joint Director designated for this purpose at district level.

e. Copy of death certificate issued by hospital/municipality or authority designated duly attested by the CMO/CDMO/CHMO/CDHMO/DMO/ DHO/Joint Director designated for this purpose at district level.

In case of tubectomy the report may include (Annexure VI):

1. Urine test report supported by physical examination report/AN card/USG report
2. MTP report
3. Physical examination report
4. USG report
5. In extreme cases birth certificate in case of full term pregnancy

II. **Claims under indemnity cover (Section II):**

1. Intimation in writing
2. Copy of summon/FIR
3. Copy of sterilization certificate
4. Copy of Consent Form
5. Certificate from CMO/CDMO/CHMO/CDHMO/DMO/DHO/Joint Director designated for this purpose at district level confirming that the sterilization operation was conducted by the doctor, etc.
6. Copy of the reward given by the court along with the original receipts for which payment is made to the lawyer.

In case, any claim is found untenable, the reason of rejection of claim will be communicated to the beneficiary by respective CMO/CDMO/CHMO/CDHMO/DMO/DHO/Joint Director of the district for this purpose with a copy to the State Nodal Officer.

ELIGIBILITY/QUALIFICATION OF DOCTORS CONDUCTING STERILISATION PROCEDURES (TUBECTOMY)

Eligibility of Providers to Perform Sterilization Procedure/Sterilization Service[6]

Empanelled female	Minilap sterilization	DGO, MD/MS in ObGyn Specialists in other surgical fields (trained in minilap sterilization), MBBS (trained in minilap sterilization)
	Laparoscopic sterilization	DGO, MD/MS in ObGyn specialists in other surgical fields (trained in laparoscopic sterilization), MBBS performing minilap sterilization (trained in laparoscopic sterilization)

Criteria for Empanelment/Accreditations of the Private Doctors/Health Facilities

All state governments and UT administrations have been asked to prepare panel of doctors/health facilities state-wise, region-wise or district-wise in accordance with the Hon'ble Supreme Court's orders.

The Family Planning Indemnity Scheme covers government doctors/Institutions and private doctors/health facilities providing family planning services to people. Empanelment/accreditation of the private sector doctor's/health facilities is essential for getting the benefits under this Scheme.

CONCLUSION

1. Every surgeon should follow the national guidelines set up by *Ministry of Health and Family Welfare, Government of India.*
2. Health facility should be registered as per the guideline for performing sterilization and OP should be empaneled as per eligibility criteria discussed above.
3. Every consent and other related documents should be signed by the patient in front of the doctor himself.
4. OP should explain to the patient if she misses her periods, she should visit the OP without any delay.

5. Life-threatening complications or complications related to failure of the procedure should be explained to patient with possible signs and symptoms before discharging the patient from health facility.
6. A surgeon should be mindful of all the possibility of complications of surgery.
   If any complication arises preoperatively or postoperatively OP should with all due care and skills should manage the patient in emergency or non-emergency situations arising out of such complication. Failing to do so, an OP can be held liable for medical negligence.
7. Postmortem and other pathology reports would confirm such possibility of injury to organ or vessels while dealing with a case of death resulting to tubectomy.
8. Patient should be immediately brought to the doctor if she develops any warning signs or symptoms of complication explained to the patient prior to discharge and such patient should be treated promptly with reasonable care and treatment.
9. The scheme provides for a framework to cope with the issue of negligence in sterilisation procedures and also gives a balanced technique and recognises the restrictions of doctor's/health facilities and affords them with an inexpensive protection. Simultaneously, it gives a legal favour to the victim as well by providing compensation to the closed one of the deceased under Section I of the Scheme.

   Family Planning Indemnity Scheme: Family Planning Indemnity Scheme indemnifies all clients of sterilization as also doctors/ health facilities conducting sterilization operation in both public and accredited private/NGO sector health facilities for unlikely events of death/complications/failure attributable to sterilization operations.

REFERENCES

1. Dutta D.C. Textbook of Gynecology, Contraception; 4th Edition, 2003; p. 459 www.Indianmedguru.com).
2. Reddy KSN. The Essential of Forensic Medicine and Toxicology; Medical Law and Ethics, 24th edition, 2005, p. 28–36.
3. Rajmal vs State of Rajasthan, AIR 1996 Raj 80 (Raj HC)
4. Achutrao Haribhau Khodwa vs State of Maharashtra, AIR 1996 SC 2377:1996(2) SCC 634.
5. Bansidhar Panigrahi vs Chief Medical Officer, Ganjam 1993(1) CPR 94 (Ori. SCDRC)
6. Reference manual for female sterilization in family planning division. Ministry of Health and Family Welfare, Government of India.

ANNEXURE I

CLAIM FORM FOR FAMILY PLANNING INDEMNITY SCHEME

The state will ensure that Claim Form-cum-medical certificate required for submitting claims under the FPIS Scheme are made available with all medical facilities conducting sterilization procedures, office of CMO/CDMO/CMHO/CDHMO/DMO/DHO/ Joint Director designated for this purpose at district level, etc. in local language along with their English version.

1. This Form is required to be completed for lodging claim under Section I of the Scheme.
2. This Form is issued without admission of liability and must be completed and returned to the District Health Society/State Health Society for processing of claim.
3. No claim can be admitted unless certified by the CMO/CDMO/CHMO/ CDHMO/DMO/DHO/Joint Director designated for this purpose at district level by the state government.

Claim no.: .....

1. Details of the claimant:

   Name in full: ..... Present Age: ..... Years
   Relationship with the acceptor of sterilization: .....
   Residential Address: .....
   .....Telephone no. .....
2. Details of the person undergone sterilization operation:

   Name in full: ..... Age: .....Years,
   Son/Daughter of: .....
   Name of the Spouse: .....
   Age of the Spouse: ..... Years, Address: .....
   .....
3. Permanent business or occupation: .....
4. Details of dependent children [S. No., Name, Age (yrs), Sex (M/F), whether unmarried, if unmarried, whether dependent]
5. a. Date of sterilization operation: .....

   b. Nature of sterilization operation:

   i. Tubectomy: .....
   ii. Vasectomy: .....
   iii. Laparoscopy: .....
   iv. MTP followed by sterilization: .....
   v. Cesarean operation followed by sterilization: .....
   vi. Any other surgery followed by sterilization: .....
6. a. Name and address of the doctor who conducted the operation: .....
   .....

b. Name and address of the hospital where operation was conducted: .....
.....

c. Nature of claim: .....

1. Failure of sterilization not leading to child birth: .....
2. Failure of sterilization leading to child birth: .....
3. Medical complication due to sterilization (state exact nature of complication):
   a. Date: .....
   b. Details of complication: .....
   c. Doctor/health facility: .....

4. Death following sterilization:
   a. Date of Admission: ..... Time: .....
   b. Date of Discharge: ..... Time: .....
   c. Date of Death: ..... Time: .....

7. Give details of any disease suffered by acceptor prior to undergoing sterilization operation:.....

I hereby declare that the particulars are true to the best of my knowledge and warrant the truth of the foregoing particulars in every respect, and I agree that if I have made, or shall make any false of untrue statement, suppression or concealment of fact, my right to the compensation shall be absolutely forfeited.

I hereby claim a sum of Rs ..... under the scheme, which I agree in full settlement of my claim and shall have no further right whatsoever to claim under the scheme.

Date: ..... Name of Acceptor/Claimant: .....

Place: ..... Signature (in full) or thumb impression .....

ANNEXURE II

MEDICAL CERTIFICATE ISSUED BY CMO/CDMO/CHMO/CDHMO/DMO/DHO/JOINT DIRECTOR DESIGNATED FOR THIS PURPOSE AT DISTRICT LEVEL

It is certified that Smt/Shri. .....
S/o/W/o: ..... r/o .....
.....
had undergone sterilization operation on ..... at .....
(hospital) and conducted by Dr ..... Qualifications .....
posted at ..... Nature of sterilization operation done:
i. Tubectomy: .....
ii. Vasectomy: .....
iii. Laparoscopy: .....
iv. MTP followed by sterilization: .....
iv Cesarean operation followed by sterilization: .....
v. Any other surgery followed by sterilization: .....

I have examined all the medical records and documents and hereby conclude that the sterilization operation is the antecedent cause of:

a. Failure of sterilization not leading to child birth (.....) (attach documentary evidence)
b. Failure of sterilization leading to child birth (.....) (attach documentary evidence)
c. Medical complication (please give the details as under)
   i. Nature of complication: .....
   ii. Period: .....
   iii. Expenses incurred for treatment of complication Rs .....
   (attach original bills/receipts/prescriptions)
d. Death of person (cause): .....
   i. Date of Admission: ..... Time: .....
   ii. Date of Discharge: ..... Time: .....
   iii. Date of Death: ..... Time: .....
   (attach death certificate)

I have further examined all the particulars stated in the claim form and are in conformity with my findings and is eligible for a compensation of Rs .....
due to ..... (cause).
Please pay Rs ..... to the beneficiary.

Documents enclosed:

a. Original claim-cum-medical certificate ( ) Signature:
b. Attested copy of sterilization certificate ( ) Name:
c. Attested copy of Consent Form ( ) Telephone no.:
d. ..... ( ) Designation:
e. ..... ( )

Date: ..... Seal

ANNEXURE III

APPLICATION-CUM-CONSENT FORM FOR STERILIZATION OPERATION

An informed consent is to be taken from all clients of sterilization before the performance of the surgery as per the consent form placed below

Name of Health Facility: .....

Client Hospital Registration Number: .....

Date: ...../...../20....

1. Name of the Client: Shri/Smt. .....
2. Name of Husband/Wife: Shri/Smt. .....
3. Address: .....
4. Contact No: .....
5. Names of all living, unmarried dependent children
   - i. ..... Age .....
   - ii. ..... Age .....
   - iii. ..... Age .....
   - iv. ..... Age .....
6. Father's name of beneficiary: Shri .....
7. Address: .....
   .....
8. Religion/Nationality: .....
9. Caste: SC/ST/General: .....
10. Status: APL/BPL: .....
11. Educational Qualifications: .....
12. Business/Occupation: .....
13. Operating Centre: .....

I, Smt/Shri ..... (client) hereby give consent for my sterilization operation. I am ever-married. My age is ..... years and my husband/wife's age is ..... years. I have ..... (Nos.) male and ..... (Nos.) female living children. The age of my youngest living child is ..... years.

a. I have decided to undergo the sterilization/re-sterilization operation on my own without any outside pressure, inducement or force. I declare that I/my spouse have/has not been sterilized previously (**not applicable in case of re-sterilization).**
b. I am aware that other methods of contraception are available to me. I know that for all practical purposes this operation is permanent and I also know that there are still some chances of failure of the operation for which the operating doctor and health facility will not be held responsible by me or by my relatives or any other person whomsoever.
c. I am aware that I am undergoing an operation, which carries an element of risk.
d. The eligibility criteria for the operation have been explained to me and I affirm that I am eligible to undergo the operation according to the criteria.
e. I agree to undergo the operation under any type of anesthesia, which the doctor/health facility thinks suitable for me and to be given other medicines as considered

appropriate by the doctor/ health facility concerned. I also give consent for any additional life-saving procedure, if required.

f. I agree to come for follow-up visits to the hospital/institution/doctor/health facility as instructed, failing which I shall be responsible for the consequences, if any.
g. If, after the sterilization operation, I experience a missed menstrual cycle, then I shall report within two weeks of the missed menstrual cycle to the doctor/health facility and may avail of the facility to get an MTP done free of cost. I shall be responsible for the consequences, if any.
h. I understand that vasectomy does not result in immediate sterilization. *I agree to come for semen examination **3 months after the operation** to confirm the success of sterilization surgery (Azoospermia) failing which I shall be responsible for the consequences, if any. **(*Applicable for male sterilization cases**.)
i. In case of complications, failures and the unlikely event of death attributable to sterilization, I/my spouse and dependent unmarried children will accept the compensation as per the existing provisions of the Government of India "Family Planning Indemnity Scheme" as full and final settlement and will not be entitled to claim any other compensation including compensation for upbringing of the child, if any, born on account of failure of sterilization, over and above the one offered, from any court of law in this regard.

I have read the above information or the above information has been read out and explained to me in my own language and that this form has the authority of a legal document.

I am aware that I have the option of deciding against the sterilization procedure at any time without sacrificing my rights to other reproductive health services.

Date: ..... Signature or Thumb Impression of the Client

Name of client: .....

Signature of witness (clients side):

Full Name: .....

Full Address: .....

.....

I am aware that client is ever-married and has 1 living child over one year of age.

Signature of ASHA/ Counsellor/Motivator: ……

Full Name: .....

Full Address: .....

.....

I certify that I have satisfied myself that:

a. Shri/Smt ..... is within the eligible age-group and is medically fit for the sterilization operation.
b. I have explained all Clauses to the client and that this form has the authority of a legal document.

c. I have filled the medical record-cum-checklist and followed the standards for sterilization procedures laid down by the Government of India.

Signature of Operating Doctor Signature of Medical Officer in-charge of the Facility

(Name of Operating Doctor) (Name of Medical Officer in-charge of the Facility)

Date: ..... Date: .....

Seal: Seal:

Denial of sertilization: I certify that Shri/Smt .....
is not a suitable client for sterilization/resterilization for the following reasons:

1. .....
2. .....

He/She has been advised the following alternative methods of contraception.

1. .....
2. .....

Date: ……..... Signature of the Doctor making the decision

Name and full Address: .....
.....

ANNEXURE IV

CERTIFICATE OF STERILIZATION

Certificate of sterilization should be issued one month after the surgery or, after the next menstrual period by the medical officer of the facility. If the client does not have her periods even after one month of surgery, rule out pregnancy before issuing sterilization certificate. For payment of compensation for undergoing sterilization operation, discharge slip/card will be considered a valid proof for undergoing sterilization operation.

Sterilization Certificate

Hospital Registration No. (IPD/OPD): .....

1. This is to certify that Smt/ Shri .....
   S/o; W/o Shri ..... working as .....
   residing at ..... has undergone minilap tubectomy (interval/post-partum/post-abortion/concurrent with other procedures)/laparoscopic tubal occulsion (interval/post-abortion/concurrent with other surgeries)/vasectomy in this facility/hospital .....
   ..... (Name of facility/hospital) on
   ..... by Dr .....
   For Female Sterilization:
2. She has resumed her menstrual cycle (LMP .....) or she has not resumed her menses within the month of sterilization but pregnancy test is negative.
   For Male Sterilization:
3. His semen examination undertaken on (Date) ..... revealed no sperm (azoospermia)
   *Strike out whichever is not applicable

She/He is therefore certified to be sterile

Signature of Medical Officer I/c

Date ..... Name: .....

Seal

Note: Client should acknowledge 'received' on the duplicate copy before receiving the original copy. The duplicate to be maintained as a record in the facility as per state norms.

ANNEXURE V

CONSENT FORM FOR STERLIZATION OPERATION-CUM-MEDICAL RECORDS

Name and address of the hospital where operation was conducted: .....

.....

Nature of claim:

1. Failure of sterilization not leading to child birth : .....
2. Failure of sterilization leading to child birth: .....
3. Medical complication due to sterilization (state exact nature of complication):
   a. Date: .....
   b. Details of complication: .....
   c. Doctor/health facility: .....
4. Death following sterilization:
   a. Date of Admission: ..... Time: .....
   b. Date of Discharge: ..... Time: .....
   c. Date of Death: ..... Time: .....
5. Give details of any disease suffered by acceptor prior to undergoing sterilization operation: .....

I hereby declare that the particulars are true to the best of my knowledge and warrant the truth of the foregoing particulars in every respect, and I agree that if I have made, or shall make any false of untrue statement, suppression or concealment of fact, my right to the compensation shall be absolutely forfeited.

I hereby claim a sum of Rs ..... under the scheme, which I agree in full settlement of my claim and shall have no further right whatsoever to claim under the Scheme.

Date: ..... Name of Accepter/Claimant: .....

Place: ..... Signature (in full) or Thumb Impression

ANNEXURE VI

CHECKLIST FOR SUBMISSION OF CLAIM AND DOCUMENTS REQUIRED UNDER FAMILY PLANNING INDEMNITY SCHEME

CHECKLIST

Before forwarding the Claim Form and other required document, it has to be checked.

A. Consent Form

1. Registration number of the beneficiary, date, and signature or thumb impression of the accepter are properly placed in respective columns.
2. Examination of patient record is filled in properly and doctor has put his signature and date.
3. Details of dependents of accepter are filled in.
4. All columns of Consent Form and medical record and checklist for female/male sterilization are filled properly.

B. Claim Form

1. Claim is submitted in a prescribed Claim Form in original.
2. Claim forwarded through medical officer/health facility conducting sterilization procedures.
3. Name and address of the accepter are same mentioned on Consent Form.
4. Signature or thumb impression of accepter is same as mentioned on Consent Form.
5. Date of sterilization is same as mentioned in the sterilization certificate and Consent Form.
6. Other details filled in are tallied with other relevant documents which are becoming part of Claim Form.
7. All columns of medical certificate which is a part of Claim Form are filled in and date, signature and seal of CMO/CDMO/CHMO/CDHMO/DMO/Joint Director designated for this purpose at district level has been placed.

C. Sterilization Certificate

1. Name of accepter is same as filled in on Consent Form.
2. Date of sterilization is mentioned under specific column.
3. Certificate issued have signature and date of issuing authority.
4. Sterilization certificate is in proper format as prescribed by the state and having registration number and date.

D. Diagnostic Report Issued for Failure of Sterilization

1. Report issued should be in a proper document, i.e. hospital case sheet/proper diagnostic report.
2. It should have registration number and date.
3. Cause detected for failure has been properly recorded by the issuing authority on the document.
4. First diagnostic report by which a failure is detected is attached.

E. Birth Certificate

1. Issued on a proper format.
2. Name of the accepter tallies with other records.
3. Date of birth has been properly recorded.
4. The certificate is signed and duly stamped with date by proper authority.

F. Complications

1. The case sheet/prescription have the name of accepter.
2. Case sheet/prescription have proper hospital registration number and date.
3. Case sheet/prescription have a date of sterilization.
4. Nature of postoperative complication has been recorded.
5. Medicines prescribed should tally with cash memo.
6. Case sheet/prescription and bills/cash memo are in original.

G. Death Certificate

1. Death certificate has been issued by the proper authority.
2. Name of diseased, date of death, etc. are rightly filled in the certificate.
3. Certificate should have registration number and date of issue and signature of issuing authority.

REQUIREMENT OF DOCUMENTS FOR CLAIMS UNDER THE SCHEME

Based on the following documents, claims shall be processed by the State Health Society/District Health Society.

Documents Under Section I

1. Death following sterilization (Section I(*a*) and I(*b*)):
   a. Claim Form-cum-medical certificate in original duly signed and stamped by the CMO/CDMO/CHMO/CDHMO/DMO/DHO/Joint Director designated for this purpose at district level.
   b. Copy of Consent Form duly attested by CMO/CDMO/CHMO/CDHMO/DMO/DHO/Joint Director designated for this purpose at district level.
   c. Copy of sterilization certificate duly attested by CMO/CDMO/CHMO/CDHMO/DMO/DHO/Joint Director designated for this purpose at district level.
   d. Copy of proof of postoperative procedure/discharge certificate duly attested by CMO/CDMO/CHMO/CDHMO/DMO/DHO/Joint Director designated for this purpose at district level.
   e. Copy of death certificate issued by hospital/municipality or authority designated duly attested by the CMO/CDMO/CHMO/CDHMO/DMO/DHO/Joint Director designated for this purpose at district level.
2. Failure of sterilization (Section I(*c*)):
   a. Claim Form-cum-medical certificate in original duly signed and stamped by the CMO/CDMO/CHMO/DMO/DHO/Joint Director designated for this purpose at district level.

b. Copy of Consent Form duly attested by CMO/CDMO/CHMO/CDHMO/DMO/DHO/Joint Director designated for this purpose at district level.
c. Copy of sterilization certificate duly attested by CMO/CDMO/CHMO/CDHMO/DMO/DHO/Joint Director designated for this purpose at district level.
d. Copy of any of the following diagnostic reports confirming failure of sterilization duly attested by CMO/CDMO/CHMO/CDHMO/DMO/DHO/Joint Director designated for this purpose at district level.

3. In case of tubectomy the report may be:
   a. Urine test report supported by physical examination report/AN card/USG report
   b. MTP report
   c. Physical examination report
   d. USG report: In extreme cases birth certificate in case of full term pregnancy

Note: No further document would be asked by the insurer under 23 (i, ii, iii) above.

ANNEXURE VII
DEATH NOTIFICATION FORM

Death Notification Form Instructions:

- The Medical Officer (MO) at the institution where the death occurred is responsible for filling out this form and notifying the convener of the District Quality Assurance Committee (DQAC) within 24 hours of death.
- The information is to be provided by telephone, telegram, or in person.

1. Date of this report (D/M/Y): .....
2. Date of death (D/M/Y): .....
3. Name of the deceased: .....
4. Age: .....
5. Sex: Female .....Male.....
6. Address of the deceased: .....
   .....
7. Name of husband/father: .....
8. Place where procedure performed (specify name of site) Camp: .....
   PP Centre: ..... PHC/CHC: .....
   District Hospital:..... Medical College and Hospital: ..... Accredited private/NGO facility: .....
9. a. Type of procedure tubectomy postpartum: .....
   Minilap: ..... Laparoscopy: .....
   Any other (specify): .....
   b. Vasectomy conventional: ..... NSV: .....
   c. Other with MTP/CS, etc. Yes: ..... No: .....
   If yes, give details: ....
10. Date of sterilization procedure (D/M/Y) ...../...../.....
11. Describe in detail what happened in chronological order. Include all symptoms and signs and describe all actions taken during the course of addressing the complication(s), beginning with the initial identification of the problem until the occurrence of death. Whenever possible record the time and date of each incident. (Use an additional sheet of paper if more space is required.)

.....	.....
.....	.....
.....	.....
.....	.....
.....	.....
.....	.....

12. Cause of death .....
    .....
13. Contributing factors (if any): .....
    .....
14. Was a postmortem examination performed? Yes: ..... No: .....
    If yes, describe the pertinent findings
    ....
    ....
    ....
    ....
    ....
    ....
15. Name and designation of surgeon who performed the sterilization operation
    .....
    .....
16. Name and address of institution where death occurred .....
    .....
    .....
17. Name and designation of reporting officer .....
    .....
    .....

Date: .....

Signature of Reporting Officer

Name: .....

Designation: .....

Proforma on Death Following Sterilization

[To be filled in by the operating surgeon]

(Death within one month of sterilization)

Instructions

a. The surgeon who performed the sterilization operation shall fill out this form within 7 days of receiving intimation of the death from the MO In-charge (I/c) of the centre where the death occurred.

b. Copies of the records and the autopsy report, and other pertinent information.

c. If available, shall be forwarded with this report (Form 2) to the convener of the DQAC.

1. a. Date of this report (D/M/Y)

   b. Type of institution where the death occurred/Name of the institution/Address Village/Town/City/District/State ...../...../.....

   Camp: .....

   PP Centre: .....

   PHC/CHC: .....

   District Hospital: .....

   Medical College and Hospital: .....

   Accredited Private Hospital/NGO Facility .....

   .....

   .....

   .....

   .....

   .....

2. Name of the person filling the report

   Designation and Signature: .....

3. Date of Sterilization (D/M/Y): ...../...../.....

4. Location where the procedure was performed

   Camp: .....

   PP Centre: .....

   PHC/CHC: .....

   District Hospital: .....

   Medical College and Hospital: .....

   Accredited private hospital/NGO facility: .....

   .....

5. Type of surgical approach minilap ..... laparoscopy .....

   Post-partum tubectomy .....

   Conventional vasectomy ..... NSV .....

   Any other (specify .....)

6. Date of Death (D/M/Y): ...../...../.....
7. Time of Death ..... a.m./p.m.
8. Client Details and Name: .....
9. Age: .....
10. Sex: Female ..... Male.....
11. Spouse's Name: .....
12. Address: .....
    .....
13. Relevant past medical history: .....
    .....
    .....
14. Pertinent preoperative physical and laboratory findings: .....
    .....
    .....
    .....
    .....

Sterilization Procedure:

15. Timing of procedure (females only) as per standards 24 hours to 7 days post-partum: .....
    Interval (42 days or more after delivery or abortion) .....
    With abortion, induced or spontaneous less than 12 weeks .....
    More than 12 weeks .....
    Any other (specify) .....
16. Type of anesthesia .....
    local with sedation .....
    Spinal/epidural .....
    General .....
17. Endotrachael intubation. Yes: .....
    No: .....
18. List all aesthetic agents, analgesics, sedatives, and muscle relaxants time given
    Drug Name/Dosage/Route .....
    .....
    .....
19. Vital signs during surgery time/BP/Pulse/Respiratory rate .....
    .....
    .....
20. Duration of surgery time of starting ..... a.m./p.m.
    Time of closure ..... a.m./p.m.
    Total time spent ..... min/hours

21. Vital signs after surgery. Time/BP/Pulse/Respiratory rate .....
.....
22. Emergency equipment/drugs available in facility as per standards, if not available, give details available ..... Not available .....
.....
.....
.....
23. Overall comments .....
.....
24. Name and Signature of Operating Surgeon .....
.....

Date Signature:

Name: .....

Designation: .....

Chapter
24

Failed Tubal Ligation: The Issues

Gouri Gore

In 1952, India became the first country in the developing world to create a state-sponsored family planning program, the National Family Planning Program. The program's primary objectives were to lower fertility rates and slow population growth as a tool to accelerate economic development.

In subsequent decades mass sterilisation programs were implemented by tubectomy and vasectomy camps. Various generations of intrauterine contraceptive devices were included and promoted by the public and private health care providers. The popularity of sterilization procedures seems to be on the decline in urban India, but still it is the most common method of family planning. Intrauterine contraceptive device (IUCD) is the second popular method. There are several medical issues related to the use of the above methods, however, in this chapter we will focus on the repercussions of failed tubal ligation.

Many cases were filed in the consumer court when accidental pregnancy was detected after tubal ligation procedure. Also there were few cases filed after vasectomy failure.

Some of the common allegations were as follows:

1. The doctor is not qualified to do the procedure
2. The possibility of failure of the procedure was not explained to the patient
3. The timing of surgery was inappropriate.

The compensation sum was demanded taking into account future expenses that will be incurred for the child born out of unwanted pregnancy. In some cases the lower courts had awarded compensation taking into account some of these points made by the petitioner. The higher fora: State or National commissions have not granted compensation only on the grounds of failure of sterilization method and subsequent accidental pregnancy. The commissions have decided the cases based on the following points:

1. It is a documented fact that tubal ligation or vasectomy operations can fail and accidental pregnancy can occur. Various textbook evidences were provided to support this fact.
2. Appropriate consent was obtained before the procedure and it mentioned failure of surgery.
3. The patient was advised about approaching the medical facility in case of a missed period after surgery, so that pregnancy (if at all) can be detected at an early stage.

4. The patient can be offered termination of pregnancy if the pregnancy falls in the gestational age approved for MTP as per the MTP Act.
5. A repeat sterilization surgery can be done along with MTP or another appropriate contraceptive method can be advised.

There was one case from Gujarat in which compensation was granted to the complainant. The case was decided due to the fact that the patient had approached the doctor when she missed the period after tubal ligation surgery, however, the doctor did not take appropriate steps to determine if she was pregnant. So, the courts held the doctor guilty of negligence because he failed in his reasonable duty to do appropriate investigations for detection of pregnancy and not due to failure of surgery.

Sterilization as a component of family planning services is largely being provided through a network of public and private sector facilities. In most states, camps are still a major source of sterilization services. There has been growing concern about the quality of sterilization services being offered, particularly at the camp facilities. The continuing high number of complications, failures and deaths following sterilizations also results in increased litigation being faced by the providers, which is another barrier in scaling up the sterilization services. Hence, to address this issue the Ministry of Health and Family Welfare launched a Family Planning Indemnity Scheme in 2013. The objective of the FPIS is to indemnify all acceptors of sterilization as also doctors conducting sterilization operations in both public and accredited private/NGO sector health facilities for unlikely events of death/complications/failure following sterilization operations.

Salient Features

1. The Family Planning Indemnity Scheme has all India coverage.
2. All persons undergoing/undergone sterilization operations in public health facility and health facilities of non-government and private sectors empanelled/accredited with District Health Authority are covered under Sections IA, IB, IC and ID of the scheme.
3. The Consent Form filled by the person at the time of enrolling himself/herself for sterilization operation duly countersigned at the medical facility shall be proof of coverage under the scheme (Annexure II).
4. The medical records and checklist for female/male sterilization should also be duly filled by the doctors/health facilities (Annexure III).
5. All the doctors/health facilities including doctors/health facilities of central, state, local-self governments, other public sectors and all the doctors/health facilities of non-government and private sectors empanelled/accredited with District Health Authority and conducting such operations are covered under Section II of the scheme. There is a stipulated criteria for empanelment of doctors/accreditations of health facilities for sterilization (Annexure IX).

These annexures are available in the manual for Family Planning Indemnity Scheme published by Ministry of Health and Family Welfare, Government of India in October 2013.

The available benefits under the Family Planning Indemnity Scheme are as under:

IA Death following sterilization (inclusive of death during process of sterilization operation) in hospital or within 7 days from the date of discharge from the hospital: Rs 2 lakh.

IB Death following sterilization within 8–30 days from the date of discharge from the hospital: Rs 50,000.

IC Failure of sterilization: Rs 30,000.

ID Cost of treatment in hospital and up to 60 days arising out of complication following sterilization operation (inclusive of complication during process of sterilization operation) from the date of discharge: Actual not exceeding Rs 25,000.

II Indemnity per doctor/health facilities but not more than 4 in a year: Up to Rs 2 lakh per claim.

Thus, the Family Planning Indemnity Scheme protects beneficiaries interest in case of tubectomy failure.

Chapter
25

Cases of Roadside Trauma

Vivekanshu Verma, Santosh Kumar Verma

Medicolegal cases (MLC) can be expressed as any case of injury, disease or infirmity or death in which law enforcing agencies have to enquire into the matter and fix the responsibility of a person or a group of persons responsible for causing the said injury, disease or infirmity or death and penalize as per the existing law of land.[1]

Medicolegal reports (MLR) are documents prepared by a government/private doctor, pertaining to injury, sexual offence, poisoning or unexplained death. It contains all the facts, observed by the doctor and his opinion drawn therefrom. His opinion must be based upon the observations made by him, and not on hearsay evidence.[2]

Common Roadside Medical Emergencies (Mostly in Midnight)

- Injury (physical/chemical/thermal/mechanical): Roadside trauma, assault
- Intoxication (alcohol/drugs of abuse): Drinking driving
- Illnesses (acute myocardial infarction, brain stroke)
- Infections (bacterial, viral, parasites)
- Immunological disorders (insect bites and stings, food allergies, drug allergies, anaphylaxis)
- Insanity (mania, psychosis)

Injury	*Intoxication*
Physical: Assault, RTA, hanging, strangulation, burn, fall from height	Chemical: Poison, drugs of abuse, toxic alcohol, poisonous plants, venomous bites and stings
Damage to anatomy: Skin, soft tissue, bone, ligament, muscle, solid organ, blood vessels	Damage to functions: Physiological and biochemical
Loss of continuity of vital tissue, skin laceration, abrasion, incised wound, stab wound, gunshot, bone fracture, ligament tear, meniscal tear, muscle laceration, arterial rupture	Loss of continuity of function of vital organs: Heart failure, respiratory failure, comatose state—brain, hepatic failure, kidney failure
Rx—maintain ABC—airway, breathing and circulation	Rx—maintain ABC—airway, breathing and circulation
Bedside point of care: X-rays, portable CT scan, ultrasound, Doppler, 2D echo, ABG, ECG, pulse oximeter, computer monitoring for vital parameters, ventilator, ECMO, IABP	Bedside point of care: ECG, ABG, urine for toxicology, alcohol breath analyser, oral swabs for drugs of abuse, thermometer, pulse oximeter, urine dipstick tests for ketones, capnography, hyperbaric oxygen therapy, ventilatory support

MEDICOLEGAL CLASSIFICATION OF WOUNDS[3]

The wounds or injuries may be classified as follows:

1. **Mechanical injuries:**
   a. Those caused by hard blunt weapons, fall or friction with rough surface, etc.:
      i. Abrasion
      ii. Bruise or contusion
      iii. Laceration
   b. Those caused by sharp-cutting and/or sharp edge of sharp cutting pointed weapons: **Incised wound**.
   c. Those caused by pointed tip of sharp cutting/blunt weapon:
      Stab wound: Which may again be subclassified as:
      i. Punctured
      ii. Penetrating
      iii. Perforating
   d. Those caused by **firearms**, e.g.
      i. Shotguns
      ii. Rifled gunshot weapons
      iii. Improvised country-made weapons.
2. **Thermal injuries:**
   i. Dry heat—burns.
   ii. Moist heat—scalds and blisters.
3. **Chemical injuries** are caused by corrosive acids or alkalis.

Legally on the Basis of Gravity of Injury

1. Simple hurt
2. Grievous hurt
3. Dangerous to life.

Section 319 and 320 IPC define hurt and grievous hurt respectively:

Section 319 IPC: Hurt: Whoever causes bodily pain, disease or infirmity to any person is said to cause hurt.

Section 320 IPC: Grievous hurt[4]

Firstly: Emasculation (penis or testis amputated/erectile dysfunction after spine injury)[4]

Secondly: Permanent privation of the sight of either eye (corneal opacity by injury/optic nerve damage/retinal detachment).[4]

Thirdly: Permanent privation of the hearing of either ear (tympanic membrane rupture/auditory nerve damage): Audiometry is needed to prove the loss.

Fourthly: Privation of any member or joint (limb amputation/kidney rupture)

Fifthly: Destruction or permanent impairing of the powers of any member or joint (muscle and tendon cut/post-traumatic contractures in limb muscles).

Sixthly: Permanent disfiguration of the head or face (acid vitriolage/cutting nose/permanent scar on face).

Seventhly: Fracture or dislocation of a bone or tooth. X-ray of dislocation and repeat X-ray after reduction of dislocated joint is necessary, as it is unique reversible grievous hurt, which cannot be proved in court without X-ray of patient.

Eighthly:

1. Any hurt which endangers life (dangerous to life)
2. Any hurt which causes the suffered to be during the space of 20 days in severe bodily pain or unable to follow his ordinary pursuits.
3. Any hurt which sufferers unable to follow his ordinary pursuits.

'Dangerous to life' injuries are those which may be fatal, if no surgical aid is available, e.g. tension pneumothorax, cardiac tamponade, liver and splenic laceration, deep incised wound in slit throat, stab wound in chest and abdomen, traumatic epidural hematoma (EDH) and acute subdural hematoma (SDH) with midline shift.

Differential Diagnosis: Intoxication, Injury and Insanity

	Drunkenness: Under the influence	*Head injury*
Face	Suffused; flushed and warm	Pale and clammy
Smell	Sweetish odor of alcohol in breath	Fetish odor of blood
Pulse	Fast and bounding	Slow and feeble
Pupils	Both pupils are same size. Contracted in coma, dilate on external stimuli and contract again. Reaction to light sluggish (McEwan's sign—change in size of pupil on painful stimulus). Horizontal gaze nystagmus +	**Anisocoria**—contracted and both pupils unequal and depends on site of injury
Breathing	Sighs, puffs, eructates	Shallow, irregular and slow
Memory	Confused	Retrograde amnesia unrelieved by time
Behaviour	Uncooperative, abusive, unresponsive, insolent, talkative	Cooperative, quiet, comatose
Effect of time	Agitation is reversed within few hours, as the alcohol goes out of body	Condition can worsens in hours, due to secondary hypoxic injury to brain

	Insanity	*head injury*
History	Of insanity present	Of head injury present
Preceding symptoms	Of insanity	Of concussion
Following symptoms	Of insanity	Of cerebral irritation and compression of the brain
Occurrence	Frequent	Only once

Time since injury–time since wounded:

Time since abrasion	
Abrasion of fresh duration	Abrasion is red with evidence of cozing of serum and a little blood. There is no scab
12 to 24 hours	The exudation dries up and reddish soft scab formation
By 2nd–3rd day	The scab is brownish
By 4th–5th day	The scab is dark brown and hard
By 6th–7th day	The scab blackish, dried up, shrinks and starts falling off from the margin which is completed within next 7 days

Time since bruise	
Fresh bruise	Skin is intact and reddish in colour
Next 3 days	Within a few hours it becomes bluish and remains bluish for about up to three days
By 4th day	It becomes brownish/bluish black—hemosiderin
By 5th–6th day	It changes to greenish discoloration—hematoidin
By 7th–8th day	It becomes yellowish—bilirubin and gradually fades away

Time since burn injury	
Fresh burn	Erythematic and formation of blister
2nd day	Erythematic around a blister or deep injury passes off
3rd day	Pus formation
By 4th–6th day	Slough formation which is shed off by the end of the first week

Practical Tips for MLC Writing in RTA

During court evidence, most common question of defence lawyer to a doctor (who made MLC) in injury case: Can this injury be caused by falling of vicitm by self, on hard and blunt surface?

1st case: Nitish Katara case: Homicidal physical assault by blunt weapon → comminuted depressed skull fracture of frontal bone by hammer.[5]

Defence lawyer proposed that it was a case of high speed RTA as victim was found by police in the bushes near roadside.

Now defence lawyer asked 1st question: Can skull fracture be caused by falling on hard and blunt surface?

Doctor replied: No.

Wound of this nature could be caused only when a moving person hits a stationary hard surface—results in 'countrecoup injury' and will result in a lesion in an area opposite to the point of impact. But no countercoup lesions found in Nitish Katara's head. Lawyer lost the case.[5]

Case law: Burn after roadside trauma or murder by assault: Can orthopedic surgeon give opinion on head injury (domain of neurosurgeon) and severity of burn (domain of plastic surgeon).

Case facts: Honor killing of victim by his girlfriend's brothers after kidnapping him from Haryana, assaulted him physically with hammer → head injury → died on spot-thrown on roadside in Noida (another state to hide crime) → burned the dead body of victim by pouring kerosene, to simulate accident → head on collision while driving and burning of vehicle due to accidental leakage of petrol tank of car. Accused burned the dead body of victim, and charred dead body was found as unknown by roadside attendants after 2 days of crime → postmortem done as unknown → doctor reported to police and did postmortem → found communicated fracture skull → victim was identified by his parents by recognizing his unburned hands (which were typically small—genetic trait of the family) → confirmed by DNA analysis.

Plaintiff: Homicidal physical assault by blunt weapon → comminuted depressed skull fracture of frontal bone by hammer, victim was thrown on roadside, and burned after his death (postmortem burn) → to hide the identity of victim and destroy the evidence of crime.

Result: Defence lawyer lost the case. Victim got justice after his death. Both accused found guilty of heinous crime of honor killing: rarest of rare offences, and convicted for imprisonment for whole life.

Discussion: Accused lawyer tried to prove that the murder was an accident. Accused Act kills the victim → accused plea to judge in court that his act was just an accident. Accused plea guilty under Section 304A IPC → death by accident. It has lesser punishment and is bailable offence, unlike murder under Section 302 of IPC → nonbailable offence.

Citation: Infamous case of honor killing of Nitish Katara: Delhi high court judgment in Vishal Yadav vs state of UP on 2 April, 2014. https://indiankanoon.org/doc/34613760/

2nd case: RTA of a 30-year-old pedestrian, crossing road and hit by vehicle on right lower limb of victim, sustaining primary impact injury: Right lower limb deformity with fracture of femur, tibia and fibula.

Now when the defence lawyer asked 1st question: Can this injury be caused by falling on hard and blunt surface?

Doctor replied: No.

If the victim would have fallen from height, than his both lower limbs would have got injured, there is not even an abrasion on left side.

Lawyer asked if victim fell on his right side laterally?

Doctor replied that he would have got injury over right side upper limbs or trunk too, along with lower limb. Lawyer lost the case.

3rd case: RTA of a car driving 25 year male, taking a turn over a crossing, hit by another car coming in high speed, sustaining whiplash injury of cervical spine, leading to paraplegia of both lower limbs.

Now the defence lawyer asked: Can this injury be caused by falling on hard and blunt surface?

Doctor replied: No. Victim had no abrasions or bruises, on any part of body. If he would have fallen, than these injuries would be sustained along with, for getting deep injury over neck. Lawyer lost the argument again.

So, I will request doctors to go through all the medical documents of the victim, before facing a defence lawyer; whose goal is to prove that accused has not directly injured the victim → victim fell by self → so no proven crime → so no financial claim for compensation, to be paid by accused.

By using common sense during court proceedings, genuine victim gets justice and compensation demanded.

MLC writing comprises of 3 parts, namely:[6]

a. **Preamble:** It includes the date, time and place of examination, name of the patient, his residential address, occupation; name of the person/police official accompanying, DDR/FIR No., informed consent of the person being examined, two marks of identification, thumb impression, etc, wherever applicable.
b. **Findings/observations:** It includes a complete description of the injuries/any other findings present; any investigations/referrals, etc. asked for.

c. **Opinion:** It includes the:
- Nature of the injury—whether simple or grievous.
- Weapon/force used—whether blunt or sharp or firearms or burns, etc.
- Duration of the injuries—based on the characteristics of the external injuries.[6]

Cases that are to be treated as medicolegal:
- All cases of injuries and burns, the circumstances of which suggest commission of an offence by somebody (irrespective of suspicion of foul play).
- All vehicular, factory or other unnatural accident cases specially when there is a likelihood of patient's death or grievous hurt.
- Cases of suspected or evident sexual assault.
- Cases of suspected or evident criminal abortion.
- Cases of unconsciousness where its cause is not natural or not clear.
- All cases of suspected or evident poisoning or intoxication.
- Cases brought dead with improper history creating suspicion of an offence.
- Cases of suspected self-infliction of injuries or attempted suicide.
- Any other case not falling under the above categories but has legal implications.

How to take history in RTA?

All Ks for easy recall
- *Kya hua* (then call ambulance)
- *Kitna chot lagi* (fatal trauma)
- *Kab hua* (fatal period)
- *Kaise hua* (Hit by vehicle: Primary, secondary)
- *Kaun hai* victim (name, age, gender)
- *Kahan* (place)
- *Kitne* persons (mass casualty)
- *Kyun* (intention—accidental/homicidal suicidal—reattempt)

In the casualty, while attending to an emergency, the doctor should understand that his first priority is to save the life of the patient. He should do everything possible to resuscitate the patient and ensure that he is out of danger. All legal formalities stand suspended till this is achieved. This has been clearly exemplified by the Hon'ble Supreme Court of India in Parmananda Katara vs Union of India.[7]

Do's and Don'ts in MLC Writing to Avoid Legal Punishment

- No overwriting in MLC, if any word corrected, it should be initiated by signature of doctor.
- MLC reports are confidential legal document, any tempering or alteration in entries, antedate entries, fabricating false evidence of crime, S.191 of IPC – punishable—7 years.
- Issuing or signing false injury certificate, S. 197 of IPC—3 years jail.
- Do not miss the court date on summons. Arrest warrant will be issued. Contempt of court, S. 228 of IPC. Punished for 6 months.

- Do not state false findings. Giving false evidence under oath, S. 199 of IPC, punishable—3 years.
- Always intimate the police about MLC promptly. Not informing police to screen offender, S. 201 of IPC, punishable—3 years.
- MLC report should be kept in safe custody, if lost/stolen. Destruction of evidence, S. 204 of IPC punishable—3 years.
- Do not rely on memory either in writing MLC reports or in giving court evidence, always review and reply.

Always refer to your medical records when preparing the report.

Doctors often perform a detailed physical examination, but make the mistake of not thoroughly documenting the examination. The old medical maxim, "If it is not documented, it was not done," should be remembered.

Remember that you may be cross-examined on your report—only write what you would be prepared to say under oath in court.

MLC reports should be prepared in duplicate preferably with ball pen.

Do not alter your report at the request of your patient or a third party—if you receive additional information, or you have made a mistake, provide a supplementary report.

Do not record the patient's history of events as 'fact', e.g. 'when asked what happened, Mr A said he was hit by a car' not 'Mr A was hit by a car'; and 'in my opinion, Ms B's depression has been caused by the reported behaviour of her husband' not; 'the behaviour of Ms B's violent and aggressive husband has caused her depression'.[9]

Common mistakes in MLC writing is wrong side of body mentioned → left limb fracture, noted as right side, relying on memory → creating confusion and ground for discrediting MLC reports by courts → disciplinary action → suspension from job and MCI notice for doctor's negligence. This can be prevented by properly proof reading. Their reports—doctor should take all the steps necessary to catch and correct all: Misspelled words, transcription errors, and grammatical mistakes.

When writing your MLC report it is important to remember that how you say it is just as important as what you are saying.

- Doctors, often inadvertently, use hedge words such as "it seems," "I think," "I believe," "it appears," "it could," "apparently," etc. in their MLC reports. These hedge words lessen the impact of their findings and conclusions.
- "Complete," "thorough," "meticulous," "exhaustive," and other such words to describe the examiner's chart review, research, or examination. These self-serving words will hold the doctor and his MLC report to an extremely high standard.
- "Appears," "presumably," "supposedly," "is said," and "evidently"—these terms imply uncertainty.
- "Obviously" and "clearly"—these terms can be used to make the doctor appear patronizing or presumptuous.
- "Malingering": Sometimes police asks for opinion on "generalized bodyache to victim patient of assault". In the majority of cases, it is usually better for the doctor to merely document exaggerated pain behaviors, inconsistencies, nonorganic

findings, and lack of objective findings rather than making a diagnosis of malingering.
- "Alleged," "credible," and other words that directly or indirectly opine on the credibility of the doctor. The doctor is a medical expert, not a credibility expert.
- "Dictated but not read" and "electronic signature": These practices make the examiner appear to be more interested in cranking out reports and collecting fees than in precision and accuracy.
- Using incorrect, imprecise, or confounding language in report will raise red flags and result in uncomfortable and unnecessary cross-examination by lawyer.[10]

In case of death of hospitalized roadside trauma victim, the treating doctor needs:
- To inform the close relatives by treating doctor.
- To inform the nearby police station about the death of the patient.
- To write the death summary.
- To fill up the form no. 2 for death report for registration at municipality along with Death Police Notification Form and postmortem notification Form.

Aadhar card helpful in sudden death due to roadside trauma, burn, found as unknown/disputed identity.

The Ministry of Home Affairs, Government of India and the Registrar of Births and Deaths, have made it mandatory to mention the following in Form 2, Death Report (Fig. 25.1). Aadhar is a 12-digit identification number the UIDAI issues to the residents of India. Aadhar card becomes very useful to establish identity for life insurance claims, as identity of burned victim remains obscured due to facial burns and burn of fingerprints, recorded in Aadhar directory and destruction of DNA due to exposure to extreme heat in fatal burn cases. It can be very helpful in future litigation for reappearance of victim after his/her claimed deaths due to roadside trauma and resulting burns (Table 25.1).

Table 25.1: Death report needs Aadhar card details[9]

Name of patients with Aadhar No.	*Father name with Aadhar No.*	*Mother name with Aadhar No.*	*Husband/wife name with Aadhar No. and age and contact detail*
Mandatory	Mandatory	Mandatory	Mandatory

- After police panchanama, to remove all catheters (central line, Foley's catheter, ET tube , NGT, vein flow) and to wrap the body in white sheet.
- Shift the body to the mortuary till further process.
- To hand over the dead body to the police for postmortem in presence of the close relatives and after PM the body handed over to the relatives.
- If the relatives denied for PM then police needs to give NOC.
- We cannot hold back the body for the outstanding payment of the hospital.

POSTMORTEM IS MANDATORY FOR ALL MEDICOLEGAL CASES

Every burn patient, if dies unnatural death shortly after registering MLC (Fig. 25.2) needs postmortem examination to establish cause of death, so that the culprit can be

Death report

Form No. 2 Legal Information

This part to be added to the Death Register

To be filled by the informant

1. Date of Death: (Enter the exact day, month and year the death took place, e.g. 1.1.2000) _____
2. Name of the Deceased: (Full name as usually written) _____
   Aadhar/UID No. deceased (if any) _____
3. Sex of the deceased: (Enter "male", "female") Do not use abbreviation _____
4. Name of Mother _____
   Aadhar/UID No. Mother (if any)
5. Name of Father _____
   Aadhar/UID No. Father (if any)

5a. Name of husband/wife _____
   Aadhar/UID No. Husband/wife (if any)

6. Age of the deceased: _____
7. Address of the deceased at the time of death: _____
8. Permanent address of the deceased: _____
9. Place of death (Tick the appropriate entry 1, 2 or 3 below and give the same of the Hospital/Institution or the address of the house where the death took place, if other place, give location):
   1. Hospital/Institution Name:
   2. House Address:
   3. Other Place:
10. Informant's name:
    Address:

After completing all columns 1 to 21, informant will put date and signature here

Date: Signature or left thumb mark of the informant

To be filled by the Registrar

Registration No.: Registration Date:
Registration Unit:
Town/Village: District:
Remarks (if any)

Name and Signature of the Registrar

Fig. 25.1: Death report needs Aadhar card details of victim and his family for correct identification[9]

punished. If body needs to cross the boundary of the municipal corporation/state then they need separate police NOC.

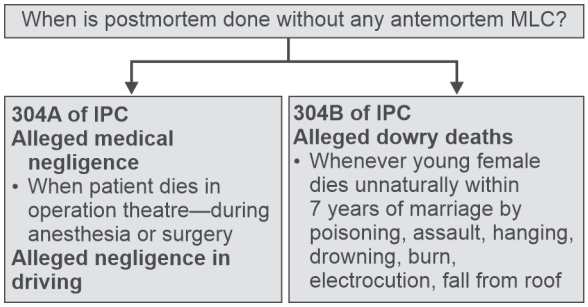

When is postmortem done without any antemortem MLC?
304A of IPC
Alleged medical negligence
• When patient dies in operation theatre—during anesthesia or surgery
Alleged negligence in driving
304B of IPC
Alleged dowry deaths
• Whenever young female dies unnaturally within 7 years of marriage by poisoning, assault, hanging, drowning, burn, electrocution, fall from roof

Fig. 25.2: When is postmortem done without any antemortem MLC

Why postmortem is done in every medicolegal case victim?

a. To find out the actual cause of death.
b. To find out the time passed since death to corroborate the day of crime.
c. To identity of the deceased, in cases where it is unknown unclaimed (Nitish Katara murder case → blunt injury head by hammer → RTA → burn → cannot identify).
d. To find out the burn injury on body before death/after death.
e. To collect relevant information to assist the investigating officers to arrive at a conclusion whether death is accidental, suicidal or homicidal.
f. In case of infants born in burned pregnant, whether it is live born/still born/dead born and, if live born the period of survival and the cause of death.
g. To collect evidence → pieces of vital organs, samples of blood and body fluids and foreign bodies → gunshot bullets → to establish the weapon of crime.
h. To opine as to whether medical attendance following burn injury was given or not (Kennedy phenomenon) → in VIP cases, e.g. John F Kennedy's assassination and Indira Gandhi's assassination → suturing and repair of wound vanished the track of gunshot wound → but still culprit was found guilty.
i. To ascertain the period of survival following receipt of burn injury.
j. To find out the time passed since death since last meal (poisoned before burn).
k. Whether the position of the dead body was changed or dragged after death.
l. To opine as to the place and circumstances of death—based on detection of modified forms of putrefaction.
m. In presence of multiple injuries—what was the number of assailants (Nirbhaya case of Delhi).
n. To connect the accused with the offence (Priyadarshini Mattu case).
o. To collect samples for chemical analysis, histological exam (Sunanda Pushkar case—polonium or alprax poisoning).
p. To opine as to whether medical attendance following injury was beneficial or deleterious, thus causing death due to medical negligence.[11]

CONCLUSION

Doctors who follow the action steps outlined above will write more precise, valuable, and defensible MLC reports.

REFERENCES

1. SR Kochar's Practical Book on MLC writing, 1st Ed, 2010.
2. VV Pillay's Textbook of Forensic Medicine & Toxicology 17th Ed, Paras Publishers, 2016.
3. RN Karmakar's Procedures for MLC Report writing, 1st Ed 2009 by Academic Publishers, Kolkata
4. PK Saraswat's Manual of MLC practice, 1st Ed 1996 by Unique Books.
5. Infamous Nitish Katara case: Delhi high court judgment in Vishal Yadav vs State of UP on 2 April, 2014.
6. Harish D, Chavali KH. The Medicolegal case. Should we be afraid of it? Anil Aggrawal's Internet Journal of Forensic Medicine and Toxicology, 2007; 8:1.
7. Parmananda Katara vs Union of India. AIR 1986, SC 2039.
8. Sara Bird. How to write a medicolegal report. Australian Family Physician, Nov 2014;43:11.
9. Requirement of Aadhar number for Registration of Death of an Individual Press Information Bureau. Government of India. Ministry of Home Affairs. https://pib.gov.in/newsite/PrintRelease.aspx?relid=169622.
10. Steven Babitsky. The 10 Biggest Mistakes Physicians Make in Writing their Medical Reports. Published in Book 'Writing and Defending Your Medical Report: The Comprehensive Guide', 1st Ed, 2012.
11. Venkatram M, Bhat S, Verma M, Sirur S Premanand. Textbook of Medicolegal Issues in Plastic Surgery and Dermatology, 1st Edition. Jaypee Publishers. Delhi. 2019. Online Link:http://www.jaypeebrothers.com/pgDetails.aspx?cat=s&book_id=9789352708970.

Chapter

26

Patient Outside Declared Hours of Practice

Sudesh Mohanlal Doshi

INTRODUCTION

In India, a doctor is expected by general public to be available 24 × 7.

Doctors are always overworked, since most of private clinics, small nursing homes and primary health centers are single doctor clinics and government hospital are always understaffed. Most of doctors are compelled to give services round the clock. This puts a tremendous strain on physical, mental and social health of the doctor. He/she never finds time to give for his family and friends. The Western concept of 40–45 working hours per week is nowhere in existence in India. Emergency branches like surgery, obstetrics, gynae and medicine have long and odd working hours.

Now the question arises is doctor legally bound to see a patient who has come outside working hours.

The law is quite clear about this. Doctors have a right to refuse a patient if he has come outside working hours provided its not an emergency.

Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002

Though a physician is not bound to treat each and every person asking his services, he should not only be ever ready to respond to the calls of the sick and the injured, but should be mindful of the high character of his mission and the responsibility he discharges in the course of his professional duties. In his treatment, he should never forget that the health and the lives of those entrusted to his care depend on his skill and attention. A physician should endeavour to add to the comfort of the sick by making his visits at the hour indicated to the patients. A physician advising a patient to seek service of another physician is acceptable, however, in case of emergency a physician must treat the patient. No physician shall arbitrarily refuse treatment to a patient. However for good reason, when a patient is suffering from an ailment which is not within the range of experience of the treating physician, the physician may refuse treatment and refer the patient to another physician.

The patient must not be neglected: A physician is free to choose whom he will serve. He should, however, respond to any request for his assistance in an emergency or whenever temperate public opinion expects the service. Once having undertaken a case, the physician should not neglect the patient, nor should he withdraw from the case without giving notice to the patient, his relatives or his responsible friends

sufficiently long in advance of his withdrawal to allow them to secure another medical attendant. No provisionally or fully registered medical practitioner shall wilfully commit an Act of negligence that may deprive his patient or patients from necessary medical care."

Public and Community Health: Physicians, especially those engaged in public health work, should enlighten the public concerning quarantine regulations and measures for the prevention of epidemic and communicable diseases. At all times the physician should notify the constituted public health authorities of every case of communicable disease under his care, in accordance with the laws, rules and regulations of the health authorities. When an epidemic occurs a physician should not abandon his duty for fear of contracting the disease himself.

In Parmanand Katara case Honourable Supreme Court has stated that every doctor whether at a government hospital or otherwise has professional obligation to extend his services with due expertise for protecting life.

Thus, it is abundantly clear that whenever a patient comes out of declared hours of practice, it is not mandatory on a doctor to examine that patient provided that it is not an emergency.

Chapter

27

Poor Facilities or Services not Available in Your Set-up

Amit Kumar, Nitin Dutt Bhardwaj, John Paul G Momin, Supriya Singh

INTRODUCTION

Modern hospitals are complex system of services; it includes OPD, IPD, emergency and diagnostic services. With origin of newer facilities like robotic surgery, telemedicine, invasive radiology; it is challenging for small hospitals of the India to provide all the services to the patients.

HEALTH CARE SYSTEM OF INDIA

There are various health care delivery systems in India. Some are multispecialty hospitals where as majority of hospitals are stand-alone centres in private. Stand-alone centres have a single speciality. These centres deal with the patients of particular speciality in emergency situations. Some hospitals have only OPD service for particular speciality or super speciality. All the details of health care delivery systems are given in Fig. 27.1. Supreme Court of India had given the guidelines for emergency care of patients after Parmanand Katara case in 1989.

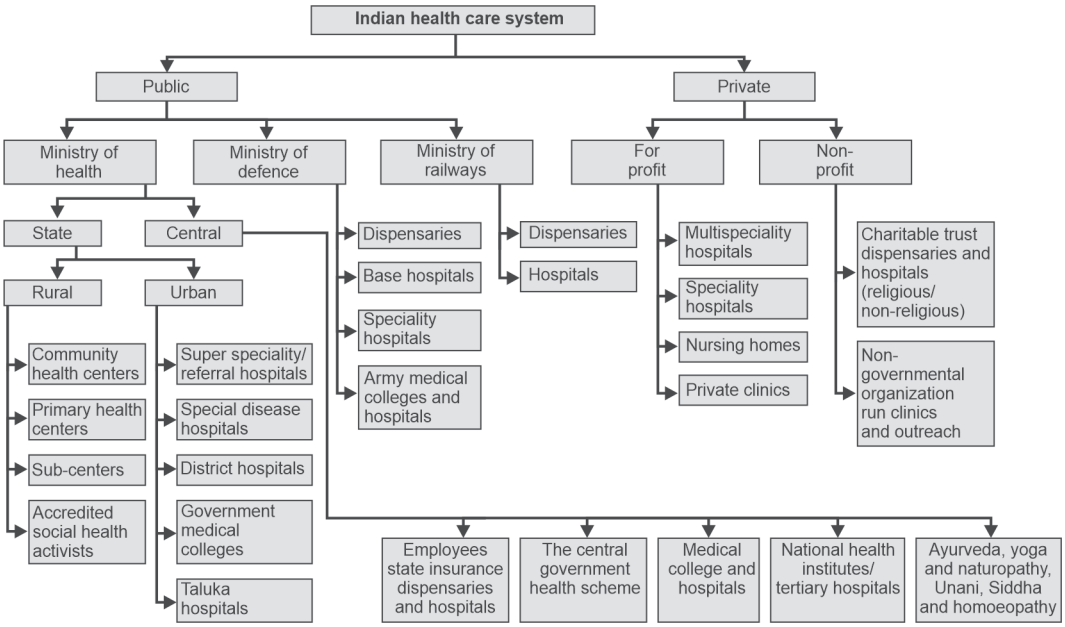


Fig. 27.1: Health care system of India

Facilities Required for Hospitals

Various facilities are required in a hospital according to level of hospital. List of facilities is described in Table 27.1.

Table 27.1: List of facilities

Facilities	*Necessary availability*
Facility provides curative services	
The facility provides general medicine services	Functional general medicine clinic Emergency medical procedures General medicine indoor services Isolation ward Intensive care services for medical cases
The facility provides general surgery services	Functional general surgery clinic Emergency surgical procedures General surgery procedures Intensive care services for surgical cases General surgery indoor services Burn ward indoor services
The facility provides obstetrics and gynecology services	Functional obstetrics and gynecology clinic Emergency obstetrics and gynecology procedures Comprehensive obstetric services Gynecology indoor services Gynecology procedures Intensive care services for gynecology and obstetrics cases
The facility provides pediatric services	Pediatric clinic Emergency pediatric procedures Dedicated pediatric ward Isolation room Functional SNCU Functional NRC Pediatric surgery procedure
The facility provides ophthalmology services	Functional ophthalmology clinic Emergency ophthalmology procedures Ophthalmic surgery procedures
The facility provides ENT services	Functional ENT clinic OPD ENT procedures Emergency ENT procedures ENT surgical procedure
The facility provides orthopedics services	Functional orthopedic clinic OPD orthopedic procedure Emergency orthopedic procedures Orthopedic surgical procedures Orthopedics indoor services
The facility provides skin and VD services	Functional skin and VD clinic
The facility provides psychiatry services	Functional psychiatry clinic Emergency psychiatric procedures Psychiatry indoor services
The facility provides dental treatment services	Functional dental clinic OPD dental procedure Oral surgery procedures
The facility provides AYUSH services	Functional AYUSH clinic

(Contd.)

Facilities	*Necessary availability*
The facility provides physiotherapy services	Functional physiotherapy unit Indoor physiotherapy procedures
The facility provides services for OPD procedures	Dressing facilities at OPD Injection room facilities at OPD Dressing room facility Injection room facilities
Services are available for the time period as mandated	At least 6 hours of OPD services are available 24 × 7 availability of dedicated emergency services Labour room services are functional 24 × 7 Availability of nursing services 24 × 7 OT services are available 24 × 7 At least 6 hours of OPD services are available at family planning clinic Days for FP surgeries are fixed Availability of ICU services 24 × 7 Blood bank services are available 24 × 7 All radiology services are available in routine working hours Emergency radiology services are available for selected procedure 24 × 7 Dispensary services are available in OPD hours Facility ensure access to drug store after OPD hours Generic drug store is operational 24 × 7 Availability of services 24 × 7
The facility provides services for superspecialties, as mandated	Functional cardiology clinic Functional gastroentomology clinic Functional nephrology clinic Functional neurology clinic Functional endocrinology clinic Functional oncology clinic Functional nuclear medicine clinic Dialysis services
The facility provides accident and emergency services	Emergency procedures Emergency OT services as and even when required Accident and trauma ward Functional A and E department Functional disaster management unit
The facility provides intensive care services	Intensive care services Functional intensive care unit
The facility provides blood bank and transfusion services	Availability/linkage with blood bank Blood bank has facility of whole blood collection and storage Blood bank has facility for blood components Blood bank has emergency stock of blood Provision of blood donation camps Availability of functional blood bank
Facility provides RMNCHA services	
The facility provides reproductive health services	Post-partum unit at the facility Emergency obstetrics and gynecology procedure Post-partum sterilization services Spacing methods of family planning Female limiting methods of family planning Male limiting method for family planning Family planning counselling and promotive services Abortion and contraception services for 1st and 2nd trimester postpartum ward

(Contd.)

Facilities	*Necessary availability*
The facility provides maternal health services	Emergency obstetrics and gynecology procedure Functional ANC clinic Vaginal delivery Assisted delivery Management of postpartum hemorrhage Management of retained placenta Septic delivery Delivery of HIV positive PW Management of PIH/eclampsia/pre-eclampsia Initial diagnosis and management of MTP and ectopic Indoor services for antenatal cases Indoor services for normal delivery Indoor services for C section Indoor services for septic cases Indoor services for eclampsia cases C section services OT for management of complications Postnatal counselling and follow-up services Transfusion services USG services for pregnant women
The facility provides newborn health services	Functional immunization clinic Newborn resuscitation Essential newborn care Prevention of hypothermia and initiation of breastfeeding Management of low birth weight infants <1800 gm and preterm Management of all sick newborn except those requiring mechanical ventilation and major surgical intervention Resuscitation Prevention of infection including management of newborn sepsis Provision of warmth Phototherapy for newborn Breastfeeding/feeding support and Kangaroo mother care (KMC) Availability/linkage to immunization services Functional SNCU
The facility provides child health services	Functional IYCF clinic Services under RBSY Triage and emergency management of pediatric cases Screening of newborn for birth defect Indoor management of severe acute malnutrition Indoor management of severe diarrhea with severe dehydration Indoor management of meningitis Indoor management of acute respiratory infections Seizures and convulsions Shock Accidental poisoning Management of hypoglycemia as per the guideline Management of hypothermia as per the guideline Management of dehydration in the children with SAM, without shock as per the guideline Management of SAM child with shock as per the guideline Management of infection is done as per the guideline

(Contd.)

Facilities	*Necessary availability*
	Management of SAM children Management of SAM in HIV exposed/HIV infected and TB infected children Provision of therapeutic feeding as per guideline Counselling on appropriate feeding, care and hygiene as per guideline Demonstration and practice-by-doing on preparation of energy dense child food using locally available item Pediatric surgical Procedure under RBSY Functional NRC Dedicated paediatric ward District early intervention centre (DEIC)
The facility provides adolescent health services	Functional ARSH clinic Abortion services for adolescent Contraception services
Facility provides diagnostic services	
The facility provides radiology services	Availability/linkage to X-ray and USG services Radiology Services are functional 24 × 7 USG and portable X-ray services C arm services Special radiography services Dental X-ray services CT scan facility
The facility provides laboratory services	Sample collection centre Emergency diagnostic tests 24 × 7 Point-of-care diagnostic test Availability/linkage with laboratory Functional side laboratory services are available Screening and crossmatching services All lab services are available in routine working hours Emergency lab services are available for selected tests of Hematology, biochemistry and serology 24 × 7 Hematology services Biochemistry services Microbiology services Cytology services Histopathology services Clinical pathology services Serology services In-house lab
The facility provides other diagnostic services, as mandated	Functional ECG services TMT services
Facility provides services as mandated in National Health Programs/State Scheme	
The facility provides services under National Vector-borne Disease Control Program as per guidelines	OPD services under NVBDCP Treatment of malaria in pregnancy Indoor management of malaria Indoor management of chikungunya Indoor management of JE Indoor services for management Tests for diagnosis of malaria (smear and RDTK) Tests for kala azar, dengue, JE, chikungunya Drugs under NVBDCP

(Contd.)

Facilities	*Necessary availability*
The facility provides services under Revised National TB Control Program as per guidelines	Functional DOTS clinic Management of pediatric tuberculosis Indoor treatment of TB patients requires hospitalization Designated microscopy centre (AFB) Drugs under RNTBCP
The facility provides services under National Leprosy Eradication Program as per guidelines	OPD services under NLEP Assessment of disability status Supply of customized footwear Reconstructive surgery Inpatient management of severely ill cases Skin smear examination Drugs under NLEP Formation of district apex group
The facility provides services under National AIDS Control Program as per guidelines	Functional ICTC HIV testing and counselling PPTCT services for HIV positive pregnant women Functional ART centre CD4 testing facility Inpatient care for cases require hospitalization ARV drugs under NACP Drugs for paediatric HIV management Functional ART centre is available
The facility provides services under National Program for prevention and control of blindness as per guidelines	Screening and early detection of visual impairment and refraction Availability of OPD procedures
The facility provides services under Mental Health Program as per guidelines	Availability of counselling centre for suicide prevention
The facility provides services under National Program for the health care of the elderly as per guidelines	Dedicated geriatric clinic
The facility provides services under National Program for prevention and control of cancer, diabetes, cardiovascular diseases and stroke (NPCDCS) as per guidelines	Functional NCD clinic is available
The facility provides services under Integrated Disease Surveillance Program as per guidelines	Hospital has system for immediate reporting of any disease outbreak authorities A nodal person is designated for collecting and reporting data to IDSP cell Hospital disseminate the list of conditions to be reported to all clinical department
The facility provides services under National Health Program for deafness	Management of case referred from PHC/CHC directly reported to hospital
The facility provides services as per State Specific Health Program	OPD services as per State Health Programs

(Contd.)

Facilities	*Necessary availability*
Facility provides support services	
The facility provides dietary services	Dietary service
The facility provides laundry services	Laundry services
The facility provides security services	Security services
The facility provides house-keeping services	Housekeeping services
The facility ensures maintenance services	Maintenance services
The facility provides pharmacy services	Dispensing of medicines and consumables for OPD patients generic drug store Storage of drugs Cold chain management services
The facility has services of medical record department	Availability of medical record services
The facility provides mortuary services	Mortuary services Dead bodies are kept till the relatives take over the bodies Dead bodies are brought to hospital for medicolegal post-mortem work Unclaimed bodies are kept until disposal is arranged Facility for pathological postmortem

Laws Related to Governing the Commissioning of Hospital

There are around seventy-two laws and acts applicable for hospitals in India. These are divided in various categories like Laws related to governing of hospital, Laws Governing Environmental Safety, Laws Governing to Sale, Storage of Drugs and Safe Medication, Laws governing management of patients and Supreme Court guidelines for emergency care, etc. Laws related to governing of hospital are given in Table 27.2.

Table 27.2: Laws for governing the commissioning of hospital

S. No.	*Name of the Law*
1.	National building code
2.	Fire Safety Act
3.	Indian Electricity Rules
4.	Lift Act
5.	Clinical Establishment Act
6.	Atomic Energy Regulatory Board Certificate
7.	Society Registration Act
8.	Environment Protection Act
9.	Pharmacy Act
10.	Drugs and Cosmetics Act
11.	PCPNDT Act

SUPREME COURT GUIDELINES FOR EMERGENCY CARE

Hospitals and medical practitioners have to initially screen the persons to decide if they require emergency medical treatment. If they do not require such treatment, the further provisions of the Act will not apply. If it is determined that the persons require emergency medical treatment, first they have to be stabilized and thereafter, they must be given treatment. If the hospital or medical practitioner does not have facilities for screening, stabilization or emergency medical treatment, the persons have to be transferred to another hospital or to a medical practitioner having such facilities. As to what safeguards have to be taken while making the transfer, like calling for the services of an ambulance or other vehicle, as to how the persons should be taken care of during transit, all these matters are provided in detail in the Bill annexed to the report. The hospitals and medical practitioners have to maintain registers of screening, stabilization, treatment or transfer.

A transfer to another medical facility will be appropriate only in those cases in which:

i. The transferring hospital provides medical treatment within its capacity that minimizes the risk to the individual's health and, in the case of a woman in labour, the health of the unborn child.
ii. The receiving facility—has available space and qualified personnel for the treatment of the individual; and has agreed to accept transfer of the individual and to provide appropriate medical treatment.
iii. The transferring hospital sends to the receiving facility, all medical records (or copies thereof) related to the emergency condition which the individual has presented that are available at the time of transfer including available history, records related to the individual's emergency medical condition, observations of signs or symptoms, preliminary diagnosis, results of diagnostic studies or telephone reports of the studies, treatment provided, results of any tests and the informed written consent or certification (or copy thereof) required under this section, and the name and address of any on-call physician who has refused or failed to appear within reasonable time to provide necessary stabilizing treatment. Other records (e.g. test results not yet available or historical records not readily available from the hospital's files) must be sent as soon as practicable after transfer.
iv. The transfer is affected through qualified personnel and transportation equipment as required, including the use of necessary and medically appropriate life support measures during the transfer.

The Law Commission of India has taken up the subject of 'Emergency Medical Care to Victims of Accidents and other Emergencies' in the light of the observations of the Supreme Court of India in Paramanand Katara vs Union of India: AIR 1989 SC 2039 and in Paschim Bangal Khel Mazdoor Samiti vs State of West Bengal: 1996(4) SCC 37 regarding the refusal of hospitals to grant emergency relief to patients who are injured in accidents and are in emergency medical condition. There are also certain judgments of the National Consumer Redressal Forum in this behalf.

CLINICAL ESTABLISHMENT ACT

As per the Act the signages should be prominently displayed at the entrance about the facility and services provided and the timings of the services. In NABH guidelines

it is mentioned that the health care services being provided are clearly defined and are in consonance with the needs of the community, each defined service should have appropriate diagnostics and treatment facilities with suitably qualified personnel who provide OPD, IPD and emergency cover, defined health care services are prominently displayed and staff are oriented to these services.

VIOLATIONS OF LAW

Globally, in the face of violations of the human right to health and the breach of ethical principles in health and medical care, citizens have resorted to the judicial–legal system, which has resulted in a process referred to as "judicialization of health care" Judicial-legal principles emerging from court judgments are referred to as public health care or social rights jurisprudence and quite often have ethical–moral overtones. Legal scholars have alluded to the influence of such jurisprudence on health care policies in several countries. In India, violations of patients' rights have escalated into a widespread systemic phenomenon on account of the low political priority given to public health in policy and planning. The major systemic challenges in healthcare are inadequate financial, human and infrastructural resources, the lack of regulatory measures to oversee the private healthcare sector, and the lack of measures aimed at protecting patients' rights. Citizens and civil society organisations have fought against violations of the right to life and dignity in healthcare by filing social action litigations in the Supreme Court of India (SCI) and high courts (HCs), and have also approached quasi-judicial/legal bodies, such as the National Consumer Dispute Redressal Commission (NCDRC). Historically, litigations related to the denial of life-saving care, including emergency medical care, in the 1980s set a precedent for healthcare litigations. This paved the way for a rudimentary judicial discourse on ethical principles in the apex court of the country. The issue of emergency medical care, which often includes dealing with life and death situations, brings into sharp focus several intersecting concerns regarding health services, the rights of patients, and the duty of the state and medical profession. The indignity caused by the refusal to treat patients in critical condition, resulting in the loss of life, undue suffering, consequent morbidity and financial loss have been challenged in courts on the ground of moral–ethical principles that form the core of the medical profession and the health care system in a welfare state.

NONAVAILABILITY OF SERVICE

Facilities like cardiology, maternity are not available in every hospital, some have only OPD facility but no IPD and emergency facility for various specialities. In public sector all speciality services are not available in rural hospitals. Some case scenarios are discussed below for nonavailability of service-

Case 1 (orthopedic centre): A 30-year-old patient Raju was brought by his relatives as a case of road traffic accident with head injury to orthopedic centre, GCS of patient was 8.

What should be done by orthopedic surgeon in this situation?

Case 2 (primary health centre): A 60-year-old patient Shyam Singh was brought by his relatives with complaints of dyspnea, fever since the past one month and weight

loss, on examination respiratory rate was found to be 40/min and blood pressure 160/100 mm Hg.

How should the medical officer proceed about in this situation?

Case 3 (ENT centre): A 65-year-old male patient Md. Arif was brought by his relatives with complaint of chest pain, he is a k/c/o hypertension and diabetes mellitus.

What should be done by ENT surgeon in this situation?

Case 4 (cardiology centre): A 5-year-old male child patient Master Anil was brought by his parents with history of ingestion of watch battery after which he developed several episodes of vomiting.

What should be done by the cardiologist in this situation?

As per the Supreme Court guidelines for emergency, any critical or emergency patient has to be stabilized before they can be referred to other centre for further treatment. In all the four case scenarios given above patient is in emergency condition so first stabilization is mandatory but no definitions/comprehensive guidelines on stabilization were provided for the same.

As per the guidelines all hospitals should have their own referral policy. Referral guidelines for public sector hospitals were available and as per guidelines patient may be transferred to community health centre, district hospital and medical college depending on the condition of patient. According to Supreme Court guidelines in private sector patient transfer or referral should be done to a centre where the facility or service is available for treatment of the disease and communication to that hospital is to be done prior to referral of the patient. Proper document enclosing the details of the treatment given to the patient must be handed over to the patient or the attendant.

Case 5 (child care centre): A 25-year-old female patient Kamla was brought by her relatives with 39 weeks 3 days pregnancy with complaint of labour pain.

What should be done by pediatrician in this situation?

As per the Supreme Court guidelines first stabilization or delivery should be done at the centre then transfer should be done to other centre but no guidelines are available as to when patient can be transferred thereafter to other centre.

CONCLUSION

The constitution incorporates provisions guaranteeing everyone's right to the highest attainable standard of physical and mental health. Article 21 of the Constitution guarantees protection of life and personal liberty to every citizen. The Supreme Court has held that the right to live with human dignity, enshrined in Article 21, derives from the directive principles of state policy and therefore includes protection of health. Further, it has also been held that the right to health is integral to the right to life and the government has a constitutional obligation to provide health facilities. No proper guidelines for stabilization are available in India. Proper signage at entrance for available services should be mentioned so that patients know about the available services.

Chapter

28

POCSO Act, 2012 and its Challenges

Sonia S Kanitkar

INTRODUCTION

India has the largest population of children in the world. As per the 2011 Census of India, there are 472 million children below the age of eighteen. Approximately 160 million children are under 6 years of age. That makes 39% of our population. Children are the softest targets of sexual violence and vulnerable to any kind of abuse. In a report, published by "the National Crime Records Bureau", reporting of crimes against children, is on the rise, which is a good sign. In 2007, government had done a study which showed that about 53% of children had suffered sexual abuse. 50% of these abuses were surprisingly done by so-called caretakers or trusted guardians of those children. Indian government is also bound by the **"UN Convention on the Rights of the Child"** and so it is our legal obligation to protect children from any form of sexual exploitation and sexual abuse. In order to enforce child protection in a better way, the government of India has brought in POCSO Act, 2012. It stands for **"Protection of children from sexual offences"**. The National Commission for Protection of Child Rights (NCPCR) has been given the duty to monitor the implementation of POCSO Act, 2012. The most difficult part of solving the issue of sexual offences, is reporting! Most of the crimes of this nature go unnoticed either because of nonreporting or lost evidence or death of the victim. POCSO Act, 2012 with all its amendments has come to be "Victim-friendly Act" where victim gets justice easily and the offender is at the receiving end.

Why Children do not Speak up about the Victimization?

- Children feel that nobody would listen to them
- Children are afraid to lose the love of the parent even if they become perpetrators.
- Some children do not want to reveal the abuse.
- Children feel that perhaps it is 'their own fault' that the abuse happened.
- The child may have been misled into believing that this is some game or part of normal relationship.
- Sometimes, excessive fear is filled into the child by threats of harming to the child/close relative.

Who are the Children at High Risk of Abuse?

- As per statistics by World Health Organization, one in every 4 girls and one in every 7 boys is sexually abused across the world. There are other factors which put one child more susceptible to sexual abuse than any other child.

- Children with disabilities like blindness, motor disabilities, etc.
- Children living in slums/huts, etc. without any security or in lower socio-economic conditions.
- Children with low confidence/no education.
- Teens with doubtful sexuality
- Children in maladjusted families with domestic violence and lack of love and protection.
- Orphans and isolated children, beggars, children of laborers, etc.

What are the Signs and Symptoms of Child Sexual Abuse?

A simple habit like food, sleep, play, study can be affected by a mishap in a child. In most of the cases the child victim is threatened of dire consequences. Therefore, he/she does not speak to anyone so the role of caregivers is utmost important here, in order to prevent unnecessary complications in the child's life. Figure 28.1 demonstrates the symptoms.

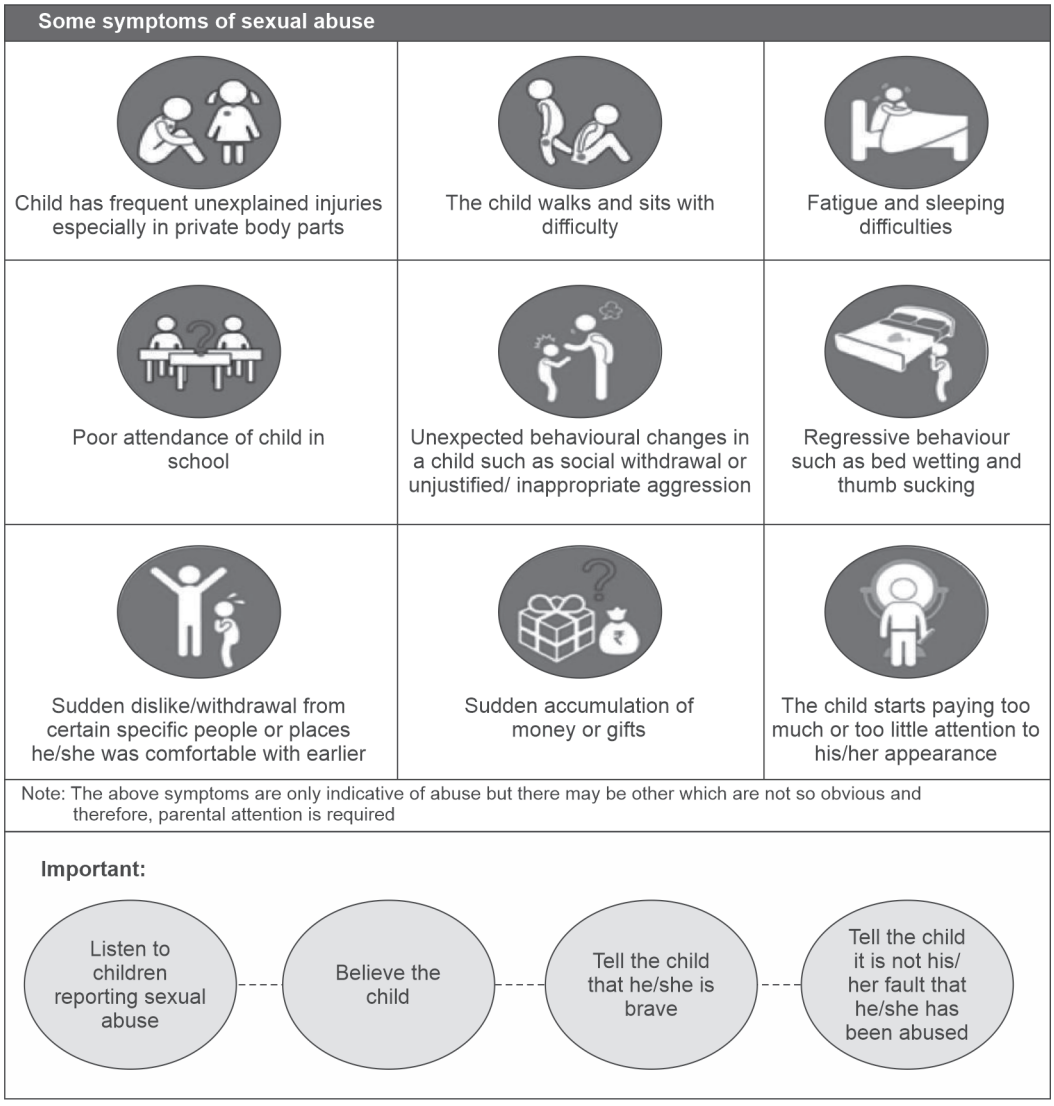

Some symptoms of sexual abuse
Child has frequent unexplained injuries especially in private body parts
The child walks and sits with difficulty
Fatigue and sleeping difficulties
Poor attendance of child in school
Unexpected behavioural changes in a child such as social withdrawal or unjustified/ inappropriate aggression
Regressive behaviour such as bed wetting and thumb sucking
Sudden dislike/withdrawal from certain specific people or places he/she was comfortable with earlier
Sudden accumulation of money or gifts
The child starts paying too much or too little attention to his/her appearance
Note: The above symptoms are only indicative of abuse but there may be other which are not so obvious and therefore, parental attention is required
Important:
Listen to children reporting sexual abuse
Believe the child
Tell the child that he/she is brave
Tell the child it is not his/her fault that he/she has been abused

Fig. 28.1: Some symptoms of sexual abuse

Keeping in mind, all the above issues, a comprehensive legislative framework has been made by the government of India to ensure prevention of child sexual abuse, protection of abused children and punishment of the offender. It is called POCSO Act, 2012. The details of the Act as follows.

THE POCSO ACT, 2012

POCSO Act, 2012 stands for **"Protection of Children against Child Sexual Offenses"**. It is an Act as per Article 15(3) of the Indian Constitution. It is a great step by the government of India as before this Act, there were no specific laws in India which dealt with children related sexual crimes in India. Also, there were no laws to punish crimes like pornography by children. Sexual crimes against male child were not even recognized by law earlier to this Act. The other issues like repeated statements by victim, delayed justice, traumatised family and their rehabilitation, were also given their due consideration in this Act. Earlier, the burden of proof, lay on the victim, but after the enforcement of POCSO, the offender has to prove innocence in the court of law.

Definitions under the POCSO Act, 2012

Relevant definitions from the Act paraphrased from the original text are as follows.

Child [Section 2 (d)]

Any person below the age of 18 years.

Penetrative Sexual Assault (Section 3)

A person is said to commit "penetrative sexual assault" if:

- He penetrates his penis, to any extent, into the vagina, mouth, urethra or anus of a child or makes the child to do so with him or any other person; or
- He inserts, to any extent, any object or a part of the body, not being the penis, into the vagina, the urethra or anus of the child or makes the child to do so with him or any other person; or
- He manipulates any part of the body of the child so as to cause penetration into the vagina, urethra, anus or any part of body of the child or makes the child to do so with him or any other person or he applies his mouth to the penis, vagina, anus, urethra of the child or makes the child to do so to such person or any other person.
- Any form of penetration in private parts or other body parts or application of the mouth to the private parts of a child or forcing the child to penetrate the offender or someone else.
- The penetration can be performed with a penis, other parts of the body or even objects.
- Manipulating the body of the child so as to cause penetration is also included.

Aggravated Penetrative Sexual Assault (Section 5)

a. Whoever, being a police officer, commits penetrative sexual assault on a child—within the limits of the police station or premises at which he is appointed; or in the premises of any station house, whether or not situated in the police station, to which he is appointed; or in the course of his duties or otherwise; or where he is known as, or identified as, a police officer; or

b. Whoever being a member of the armed forces or security forces commits penetrative sexual assault:
   i. within the limits of the area to which the person is deployed; or
   ii. in any areas under the command of the forces or armed forces; or under Section 19 of the POCSO Act, 'reporting of offences' by any person including the child has been made mandatory. Section 21 of the Act provides punishment for failure to report or record a child sexual abuse case. However, a child cannot be punished for failure to report in the course of his duties or otherwise; or
   iii. where the said person is known or identified as a member of the security or armed forces.
c. Whoever being a public servant commits penetrative sexual assault on a child; or
d. Whoever being on the management or on the staff of a jail, remand home, protection home, observation home, or other place of custody or care and protection established by or under any law for the time being in force, commits penetrative sexual assault on a child; or
e. Whoever being on the management or staff of a hospital, whether government or private, commits penetrative sexual assault on a child in that hospital; or
f. Whoever being on the management or staff of an educational institution or religious institution, commits penetrative sexual assault on a child in that institution; or

   Explanation: When a child is subjected to sexual assault by one or more persons of a group in furtherance of their common intention, each of such persons shall be deemed to have committed gang penetrative sexual assault within the meaning of this clause and each of such person shall be liable for that Act in the same manner as if it were done by him alone; or
g. Whoever commits gang penetrative sexual assault on a child.
h. Whoever commits penetrative sexual assault on a child using deadly weapons, fire, heated substance or corrosive substance; or
i. Whoever commits penetrative sexual assault causing grievous hurt or causing bodily harm and injury or injury to the sexual organs of the child; or
j. Whoever commits penetrative sexual assault on a child:
   i. physically incapacitates the child or causes the child to become mentally ill as defined under Clause (b) of Section 2 of the Mental Health Act, 1987 or causes impairment of any kind so as to render the child unable to perform regular tasks, temporarily or permanently; or
   ii. in the case of female child, makes the child pregnant as a consequence of sexual assault; or
   iii. inflicts the child with human immunodeficiency virus (HIV) or any other life-threatening disease or infection which may either temporarily or permanently impair the child by rendering him physically incapacitated, or mentally ill to perform regular tasks.
k. Whoever, taking advantage of a child's mental or physical disability, commits penetrative sexual assault on the child; or
l. Whoever commits penetrative sexual assault on the child more than once or repeatedly; or

m. Whoever commits penetrative sexual assault on a child below twelve years; or
n. Whoever being a relative of the child through blood or adoption or marriage or guardianship or in foster care or having a domestic relationship with a parent of the child or who is living in the same or shared household with the child, commits penetrative sexual assault on such child; or
o. Whoever being, in the ownership, or management, or staff, of any institution providing services to the child, commits penetrative sexual assault on the child; or
p. Whoever being in a position of trust or authority of a child commits penetrative sexual assault on the child in an institution or home of the child or anywhere else; or
q. Whoever commits penetrative sexual assault on a child knowing the child is pregnant; or
r. Whoever commits penetrative sexual assault on a child and attempts to murder the child; or
s. Whoever commits penetrative sexual assault on a child in the course of communal or sectarian violence; or
t. Whoever commits penetrative sexual assault on a child and who has been previously convicted of having committed any offence under this Act or any sexual offence punishable under any other law for the time being in force; or
u. Whoever commits penetrative sexual assault on a child and makes the child to strip or parade naked in public, is said to commit aggravated penetrative sexual assault.

When penetrative sexual assault is committed by a person in a position of trust or authority such as police officer or a member of security forces or public servant, etc. Sexual assault on a child during extraordinary circumstances like a communal or sectarian violence—is also an aggravated crime.

Sexual Assault (Section 7)

Whoever, with sexual intent touches the vagina, penis, anus or breast of the child or makes the child touch the vagina, penis, anus or breast of such person or any other person, or does any other Act with sexual intent which involves physical contact without penetration is said to commit sexual assault.

All Acts of physical nature without penetration. For example, stalking a child, showing dirty pictures, touching private parts of a child or making a child touch the private parts of someone else, etc. are covered under sexual assault.

It also includes any other Act committed with sexual intent, which involves physical contact without penetration.

Aggravated Sexual Assault (Section 9)

a. Whoever, being a police officer, commits sexual assault on a child:
   i. within the limits of the police station or premises where he is appointed; or
   ii. in the premises of any station house whether or not situated in the police station to which appointed; or
   iii. in the course of his duties or otherwise; or
   iv. where he is known as, or identified as a police officer.

b. Whoever, being a member of the armed forces or security forces, commits sexual assault on a child:
   i. within the limits of the area to which the person is deployed; or
   ii. in any areas under the command of the security or armed forces; or
   iii. in the course of his duties or otherwise; or
   iv. where he is known or identified as a member of the security or armed forces.
c. Whoever being a public servant commits sexual assault on a child; or
d. Whoever being on the management or on the staff of a jail, or remand home or protection home or observation home, or other place of custody or care and protection established by or under any law for the time being in force commits sexual assault on a child being inmate of such jail or remand home or protection home or observation home or other place of custody or care and protection; or
e. Whoever being on the management or staff of a hospital, whether government or private, commits sexual assault on a child in that hospital; or
f. Whoever being on the management or staff of an educational institution or religious institution, commits sexual assault on a child in that institution; or
g. Whoever commits gang sexual assault on a child. Explanation: When a child is subjected to sexual assault by one or more persons of a group in furtherance of their common intention, each of such persons shall be deemed to have committed gang sexual assault within the meaning of this clause and each of such person shall be liable for that Act in the same manner as if it were done by him alone; or
h. Whoever commits sexual assault on a child using deadly weapons, fire, heated substance or corrosive substance; or
i. Whoever commits sexual assault causing grievous hurt or causing bodily harm and injury or injury to the sexual organs of the child; or
j. Whoever commits sexual assault on a child, which:
   i. physically incapacitates the child or causes the child to become mentally ill as defined under Clause (l) of Section 2 of the Mental Health Act, 1987 or causes impairment of any kind so as to render the child unable to perform regular tasks, temporarily or permanently; or
   ii. inflicts the child with human immunodeficiency virus or any other life-threatening disease or infection which may either temporarily or permanently impair the child by rendering him physically incapacitated, or mentally ill to perform regular tasks.
k. Whoever, taking advantage of a child's mental or physical disability, commits sexual assault on the child; or
l. Whoever commits sexual assault on the child more than once or repeatedly; or
m. Whoever commits sexual assault on a child below twelve years; or
n. Whoever, being a relative of the child through blood or adoption or marriage or guardianship or in foster care, or having domestic relationship with a parent of the child, or who is living in the same or shared household with the child, commits sexual assault on such child; or

o. Whoever, being in the ownership or management or staff, of any institution providing services to the child, commits sexual assault on the child in such institution; or
p. Whoever, being in a position of trust or authority of a child, commits sexual assault on the child in an institution or home of the child or anywhere else; or
q. Whoever commits sexual assault on a child knowing the child is pregnant; or
r. Whoever commits sexual assault on a child and attempts to murder the child; or
s. Whoever commits sexual assault on a child in the course of communal or sectarian violence; or
t. Whoever commits sexual assault on a child and who has been previously convicted of having committed any offence under this Act or any sexual offence punishable under any other law for the time being in force; or
u. Whoever commits sexual assault on a child and makes the child to strip or parade naked in public, is said to commit aggravated sexual assault and offences of sexual assault if committed by a person in a position of power, authority and trust or in certain circumstances. When penetrative sexual assault is committed by a person in a position of trust or authority such as police officer or a member of security forces or public servant, etc.

Sexual Harassment (Section 11)

A person is said to commit sexual harassment upon a child when such person with sexual intent:

i. Utters any word or makes any sound, or makes any gesture or exhibits any object or part of body with the intention that such word or sound shall be heard, or such gesture or object or part of body shall be seen by the child; or
ii. Makes a child exhibits his body or any part of his body so as it is seen by such person or any other person; or
iii. Shows any object to a child in any form or media for pornographic purposes; or
iv. Repeatedly or constantly follows or watches or contacts a child either directly or through electronic, digital or any other means; or
v. Threatens to use, in any form of media, a real or fabricated depiction through electronic, film or digital or any other mode, of any part of the body of the child or the involvement of the child in a Sexual Act; or
vi. Entices a child for pornographic purposes or gives gratification therefor.

It also includes constantly following or watching the child either directly or through digital or any other means and also showing any object to the child in any form or enticing the child for pornographic purpose.

Abetment (Section 16)

A person abets an offence, who:

First: Instigates any person to do that offence; or

Secondly: Engages with one or more other person or persons in any conspiracy for the doing of that offence, if an Act or illegal omission takes place in pursuance of that conspiracy, and in order to the doing of that offence; or

Thirdly: Intentionally aids, by any Act or illegal omission, the doing of that offence.

Explanation I: A person who, by wilful misrepresentation, or by wilful concealment of a material fact, which he is bound to disclose, voluntarily causes or procures, or attempts to cause or procure a thing to be done, is said to instigate the doing of that offence.

Explanation II: Whoever, either prior to or at the time of commission of an Act, does anything in order to facilitate the commission of that Act, and thereby facilitates the commission thereof, is said to aid the doing of that Act.

Explanation III: Whoever employ, harbours, receives or transports a child, by means of threat or use of force or other forms of coercion, abduction, fraud, deception, abuse of power or of a position, vulnerability or the giving or receiving of payments or benefits to achieve the consent of a person having control over another person, for the purpose of any offence under this Act, is said to aid the doing of that Act.

Intentionally instigates, aids by any Act or illegal omission, the doing of that offence or be part of a conspiracy with others.

Punishment for Attempt to Commit an Offence (Section 18)

Whoever attempts to commit any offence punishable under this Act or to cause such an offence to be committed, and in such attempt, does any Act towards the commission of the offence, shall be punished with imprisonment of any description provided for the offence, for a term which may extend to one half of the imprisonment for life or, as the case may be, one-half of the longest term of imprisonment provided for that offence or with fine or with both.

Main Features of POCSO Act

i. The burden of proving the crime has been shifted onto the accused and the accused now needs to prove that he/she is innocent.
ii. POCSO Act is gender-neutral law, wherein the law takes cognizance of sexual crimes committed against both girls and boys under the age of 18 years.
iii. The law now protects children from both physical and or non-physical contact forms of abuse, e.g. pornography or even bad touch.
iv. This Act has introduced the use of child-friendly measures like special courts and video recording, etc. in order to reduce the trauma to the victim which arises out of repeated narration of the crime.
v. The Act also provides support to the child and family in the form of support person from child welfare committee and also requires counselling of the members to help them cope as well as beware of their rights.
vi. The most important feature of POCSO Act is the mandatory reporting of any sexual offence by every citizen of India who comes to know about the crime. It goes to the extent of making non-reporting punishable.
vii. All procedures are to be victim-friendly and confidentiality of the victim and family, is utmost. Media cannot reveal the identity or whereabouts of the victim in any way and any deviation, deliberate or not, is punishable.
viii. It is made possible by the Act to resolve the case within 1 year even if accused not identified.
ix. It ensures punishment to all accused irrespective of age/gender.
x. As per the Act, any case of sexual offence is given the status of medicolegal emergency.

PRACTICAL APPLICATION OF POCSO IN A CASE STUDY

A 17-year-old girl is brought to your clinic for missed periods for last 3 months. What is the role of a medical professional as per POCSO Act, 2012?

Step 1: As per POCSO Act, 2012 definition, this is a child less than 18 years. Once confirmation of pregnancy is done and the doctor has ruled out any other disease causing amenorrhea in this child, the medical professional must treat this as a case of sexual offence. The Act is clear about the duty of a person or doctor to report the case to police or Child Welfare Committee (CWC) mandatorily, even if parents do not consent to reporting. However, it is good on the part of the doctor to inform parents about the mandatory reporting.

Present case scenario: The doctor has to first report to the police, once pregnacy test confirms pregnancy.

Step 2: According to Guidelines and Protocol of Ministry of Health and Family Welfare, this is a medicolegal emergency:

1. Non-reporting is a punishable offence under POCSO Act, 2012. *Punishment can be anything from six month to a year with or without fine*.
2. Not providing first aid medical treatment is a medical offence under Criminal Amendment Law Act, 2013.
3. Punishment for abetment/supporting/encouraging the act is equal to the offence being done in person.
4. All the first aid medical expenses have to be provided free.
5. Informed consent is required for:
   a. History taking
   b. Medical examination
   c. Forensic examination and sample collection.
   d. Police intimation (reporting is compulsory).
6. Document of consent is to be signed by 3 persons—survivor, a witness and examining doctor. Two identification marks and left thumb impression need to be recorded. Below 18 years, consent to be signed by parents or trustworthy guardian present.

Present case scenario: Informed consent needs to be taken from the victim and the parents, for history as well as examination. Counselling may be required before consent is given. If consent not given then guidance for further management is to be discussed. Help can be sought from agency like CWC for counselling and further management of this girl.

Step 3: The doctor should take a detailed medical history including the exact experiences of the child. It should be recorded in exact words as told by the victim. The history should be obtained in non-judgmental and empathetic manner.

How to document history?

- Date, time and location of incidence have to be recorded
- Who is narrating—survivor or informant ?
- In survivors own words'—even exclamations/all expressed words are very important in court of law.
- Relevant medical and surgical history is usually to be asked.
- Menstrual history—length, duration, LMP, whether survivor was menstruating at the time of incidence.

- Vaccination history: Tetanus and hepatitis B are most essential to be enquired first.
- Sexual violence history: Record each word like 'negative' and 'not so sure', etc. as per the commentary of the victim. Each expression, exclamation and word spoken by the victim is important in the eyes of law.

Present case scenario: Record the history and document it by getting it signed by the girl, the mother and the doctor.

Step 4: A thorough medical examination needs to be done including the local examination of the genitalia. Only female doctor can examine the victim girl as per POCSO Act, 2012, Section 27(2). But in special situations, when female doctor is not available then with consent and in presence of female guardian, male doctor can examine, as per guidelines of Ministry of Health and Family Welfare (2014). A trusted chaperon can be present along with the male doctor. No police personnel should be around during examination.

Present case scenario: The doctor needs to do:

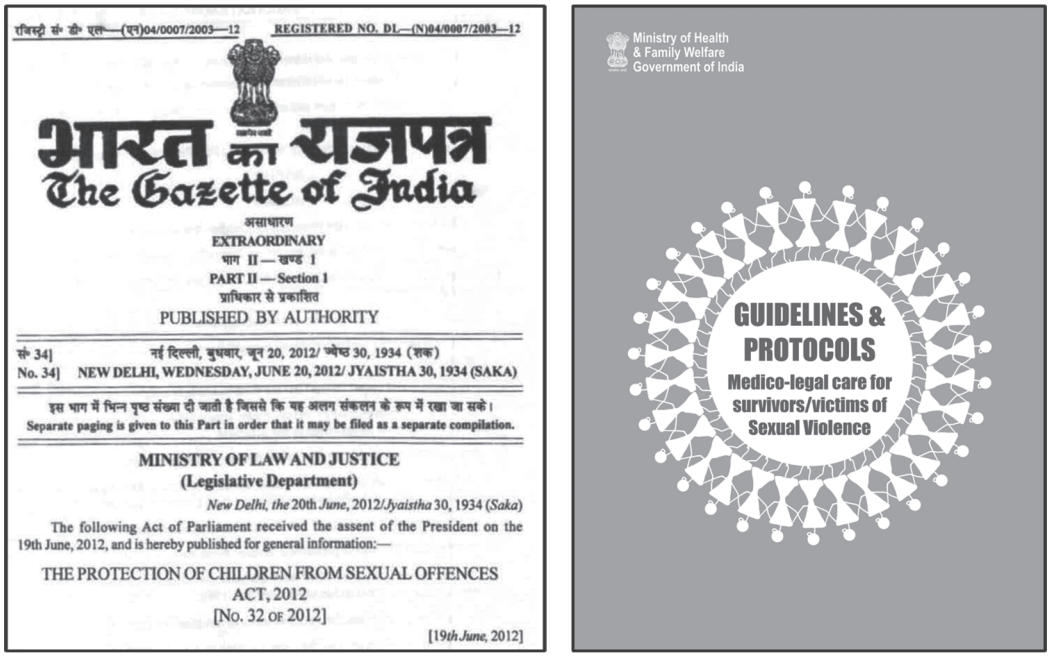
a. **General examination:** Victim's orientation, mental state, consciousness, physical state, clothing status (original/changed), any other incidental observation.
b. **Special examination:** Specific area examination with all scratches, bruises, injuries to be recorded in details. Thorough examination of genital organs, external and internal organs have to be done. Per vaginal examination need not be done in this case.

Step 5: Evidence collection is a very important part of POCSO Act: If examined within 96 hours of incidence, all clothings and swabs should be air dried and preserved. All hospital should have safe kit (sexual assault forensic evidence kit), which contains all essential tools and instruments for collection of samples and other situational evidences.Collect materials, swabs and samples for DNA profiling/forensic evidence from hair, nails, body surfaces or orifices, any product of conception, before washing /cleaning/before the child urinates/defecates. Collect blood samples for intoxicants and blood group. Ensure proper labeling, storage, preservation and proper handover to the authorized personnel after getting signature of receipt from the person taking the evidences.

Present case scenario: In this case also, whatever samples from the genitalia or clothes, etc. are present, they need to be collected and preserved till handed over to police personnel after getting acknowledgement from the receiving party.

Step 6: In acute cases, first aid and treatment of physical and genital injuries needs to be done immediately before history, etc. In some cases, age assessment is important. In any case of sexual offence, prophylaxis for sexually transmitted diseases and HIV needs to be told to the victim. Sometimes emergency contraceptives can save a child from the complication of sexual abuse. During treatment, mental health needs to be treated in a patient manner. Help by a counsellor or psychiatrist can be sought. Family counselling is an integral part of treatment by the doctor. It is important to make the family aware of their rights and duties in such situations. This helps the victim and the family to cope and also testify in the court of law.

Present case scenario: Since there are no gross injuries, this girl needs to be offered treatment of STDs, vaccination especially hepatitis B and tetanus (if not done already), treatment of local genital bruises or infection if present. Psychotherapy and family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No. 34] NEW DELHI, WEDNESDAY, JUNE 20, 2012/ JYAISTHA 30, 1934 (SAKA)
इस भाग में भिन्न पृष्ठ संख्या दी जाती है जिससे कि यह अलग संकलन के रूप में रखा जा सके।
Separate paging is given to this Part in order that it may be filed as a separate compilation.
MINISTRY OF LAW AND JUSTICE
(Legislative Department)
New Delhi, the 20th June, 2012/Jyaistha 30, 1934 (Saka)
The following Act of Parliament received the assent of the President on the 19th June, 2012, and is hereby published for general information:—
THE PROTECTION OF CHILDREN FROM SEXUAL OFFENCES ACT, 2012
[No. 32 OF 2012]
[19th June, 2012]
Ministry of Health & Family Welfare Government of India
GUIDELINES & PROTOCOLS
Medico-legal care for survivors/victims of Sexual Violence

Fig. 28.2: The POCSO Act and the guidelines

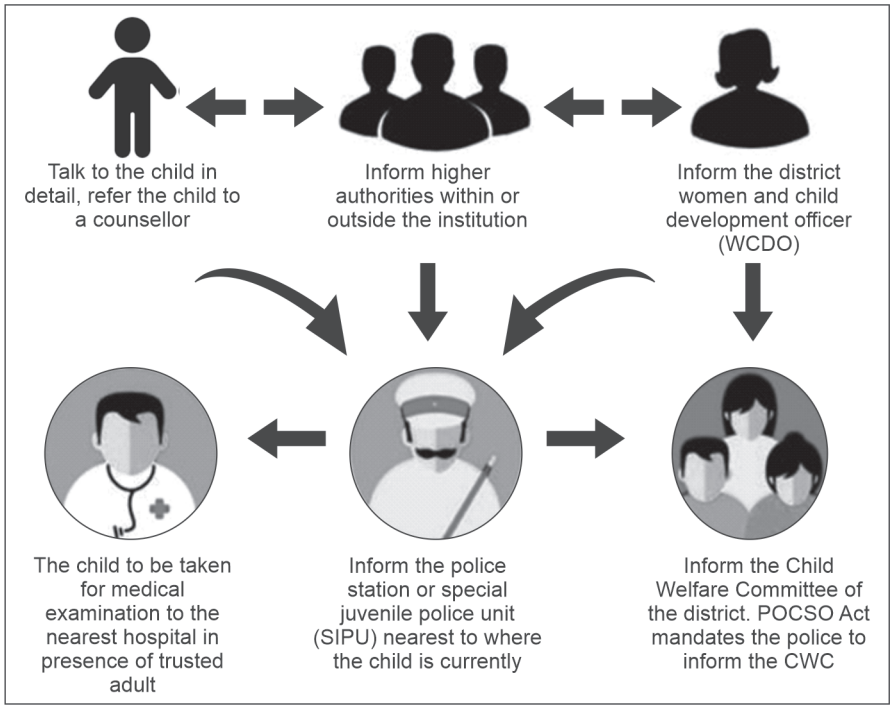
Talk to the child in detail, refer the child to a counsellor
Inform higher authorities within or outside the institution
Inform the district women and child development officer (WCDO)
The child to be taken for medical examination to the nearest hospital in presence of trusted adult
Inform the police station or special juvenile police unit (SIPU) nearest to where the child is currently
Inform the Child Welfare Committee of the district. POCSO Act mandates the police to inform the CWC

Fig. 28.3: The steps to be taken

counselling as required. Definitely this girl needs a gynecologist to do further assessment and management of pregnancy, after consent for treatment. If appropriate consent is not for treatment, then help of a family counsellor or Child Welfare Committee or special juvenile police unit (SJPU) can be sought.

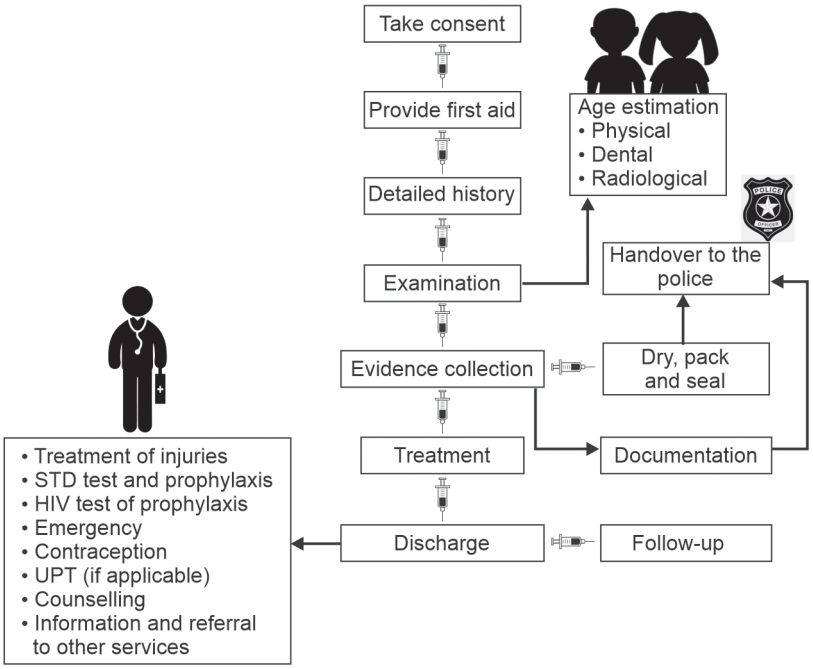

Fig. 28.4: A quick glance at steps to be followed during medical examination of the child victims of sexual violence

CHALLENGES OF POCSO ACT

1. **Consent:** When child/adolescent does not want to get medical examination done, but the family/guardian is persuading the doctor for examination, in such a situation, there are no clear cut guidelines in POCSO Act, 2012.
2. **Medical examination:** It is compulsory for a female doctor to do the medical examination in a girl child, as per Section 27(2) of the POCSO Act. But Section 166A of Indian Penal Code, makes it compulsory for the doctor on duty (whether male/female) to carry out the medical examination and give emergency medical care. This gives rise to a conflicting situation when female doctor is unavailable.
3. **Treatment cost:** Sometimes the immediate medical care required may be costly, but as per POCSO, immediate treatment needs to be provided free. This may lead to mismanagement on the part of hospitals.
4. **Sexual intercourse by mutual consent:** POCSO has given a blanket statement regading sexual intimacy between any child below 18 years, but sometimes adolescents indulge in such activities by mutual consent. POCSO has no provision or exception for such cases. This creates difficult situation for doctors as the adolescents trust their doctors and confide in them. Also, any MTP (Medical Termination of Pregnancy) needs to be compulsorily reported. This may increase the risk of unlawful, self-induced abortions.
5. **Child marriage:** The issue of child marriage needs to be dealt with considering its rampant presence in Indian rural population.
6. **Awareness and education:** The POCSO Act, 2012, though in force, is hardly known to healthcare workers, even doctors and police personnel. There is a real

need to have educative programs to create awareness and appropriate knowledge about this Act.

7. **Special mental health care:** sexual offences have an inbuilt mental trauma attached with them. The psychology of the victim and the criminal need a special training and not all doctors or healthcare workers and police can handle situations of such magnitude. Thus, special training for handling cases of acute or chronic sexual offences, need to be undertaken by the government.
8. **Reporting:** Sexual offences have been for ages, under reported, for fear of public shame. POCSO Act, 2012 does not have any flexibility for family decision or time to think or need for police involvement. POCSO does not have any consideration for the highly personal nature of this offence.

As medical professional and as trusted caretakers, we all need to follow a balance approach. Reporting should be done only once we are sure about the sexual offence and not just on doubtful circumstances. We need to be vigilant while observing, assessing and concluding in a case of sexual abuse.

POCSO is an excellent tool against this age old heinous crime, but it needs to be sensitive to certain issues and the need to give a relook at it and make amendments.

REFERENCES

1. Krishnakumar P, Satheesan K, Geeta MG, Sureshkumar K. Prevalence and spectrum of sexual abuse among adolescents in Kerala, South India. *Indian J Pediatr* 2014;81:770–4. [PubMed].
2. Ministry of Women and Child Development; Government of India. Study on child abuse India, 2007. [Accessed on October 10, 2014]. Available from: http://www.wcd.nic.in/childabuse.pdf.
3. Dhawan J, Gupta S, Kumar B. Sexually transmitted diseases in children in India. *Indian J Dermatol Venereol Leprol* 2010;76:489–93. [PubMed].
4. Karthiga RK, Ravikumar R. Child sexual abuse in Madurai, India: a literary review and empirical study. *J Child Sex Abuse* 2014;23:727–44. [PubMed].
5. Ministry of Women and Child Development. Model guidelines under Section 39 of the Protection of Children from Sexual Offences Act, 2012. [Accessed on October 13, 2014]. Available from: http://wcd.nic.in/act/POCSO%20-%20Model%20Guidelines.pdf .
6. The Protection of Children from Sexual Offences Act, 2012. [Accessed on October 10, 2014]. Available from: http://wcd.nic.in/childact/childprotection31072012.pdf .
7. POCSO Act: Providing Child-Friendly Judicial Process. Press information Bureau, Government of India. [Accessed on October 13, 2014]. Available from: http://pib.nic.in/newsite/efeatures.aspx.?relid=86150.
8. The Criminal Law (Amendment), 2013. [accessed on October 10, 2014]. Available from: http://indiacode.nic.in/acts-in-pdf/132013.pdf.
9. Behere PB, Sathyanarayana Rao TS, Mulmule AN. Sexual abuse in women with special reference to children: barriers, boundaries and beyond. *Indian J* 2013;55:316–9. [PMC free article] [PubMed].
10. Raha S, Giliyal A. Child Marriage and the Protection of Children from Sexual Offences Act, 2012. Centre for Child and the Law (CCL) and National Law School of India University (NLSIU) [Accessed on October 10, 2014]. Available from: https://www.nls.ac.in/ccl/justicetochildren/poscoact.pdf.
11. Adams JA, Harper K, Knudson S, Revilla J. Examination findings in legally confirmed child sexual abuse: it's normal to be normal. *Pediatrics* 1994;94:310–7. [PubMed].
12. Sathyanarayana Rao TS, Nagpal M, Andrade C. Sexual coercion: time to rise to the challenge. *Indian J Psychiatry* 2013;55:211–3. [PMC free article] [PubMed].
13. Harbishettar V, Math SB. Violence against women in India: comprehensive care for survivors. *Indian J Med Res* 2014;140:111–3. [PMC free article] [PubMed].
14. Handbook of POCSO at www.ncpcr.gov.in accessed on 26th December 2019.
15. Website https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4557243 accessed on 28th December 2019.

Section

6

Negligence

29. Wrong Diagnosis: Does it Amount to Medical Negligence?
30. Error, Imperfection and Unexpected Outcome
31. Informed Consent: Is it Must?
32. Medical Documentation

Section Editors: Indranil Choudhary, Prabhuddha Mittal, Kundan Mittal

Chapter

29

Wrong Diagnosis: Does it Amount to Medical Negligence?

Virender Pal Singh

WRONG DIAGNOSIS

To provide reasonable and effective care to the patient, it is very important to establish the correct diagnosis of the disease. The errors in diagnosis may include delayed diagnosis, missed diagnosis, and the wrong diagnosis.

- Such errors in diagnosis may lead to:
  1. Inappropriate diagnostic tests
  2. Failure to advise appropriate diagnostic tests
  3. Misinterpretation of test results
  4. An inappropriate treatment choice
  5. Failure of treatment or undesired harmful effects of treatment.
- The consequences of diagnostic errors can be far-reaching and may amount to medical negligence.

WHAT IS MEDICAL NEGLIGENCE?

- The definition of negligence as used in **Kusum Sharma and others vs Batra Hospital and Medical Research Centre and others**[1] case is:
  Negligence: *Duties owed to patient*: "A person who holds himself out as ready to give medical advice or treatment impliedly undertakes that he is possessed of skill and knowledge for the purpose. Such a person must be a registered medical practitioner, who is consulted by a patient, owes him certain duties, namely a duty of care in deciding whether to undertake the case; a duty of care in deciding what treatment to give; and a duty of care in his administration of that treatment. A breach of any of these duties will support an action for negligence by the patient."
- **Bolam's rule:** The Bolam's rule is very useful in deciding medical negligence for the medical professional. The Indian courts routinely apply Bolam's rule in deciding the medical negligence cases. The **Bolam vs Friern Hospital Management Committee**[2] judgement states that a doctor cannot be said to be negligent if he is acting in accordance with a practice accepted as proper by a reasonable body of medical men skilled in that particular art, merely because there is a body of such opinion that takes a contrary view. Additionaly, it adds that the test of negligence cannot be the test of the man on the top of a Clapham omnibus. Further on, in cases

of medical negligence, where a special skill or competence is attributed to a doctor, a doctor need not possess the highest expert skill, at the risk of being found negligent, and it would suffice if he exercises the ordinary skill of an ordinary competent man exercising that particular art.

- In **Jacob Mathew vs State of Punjab**[3], the Supreme Court dealt with the law of negligence with respect of professionals professing some special skills. It states that any individual approaching such a skilled person would have a reasonable expectation of a degree of care and caution, however, there could be no assurance of the result. A physician, thus, would not assure a full recovery in every case. On the other hand, implied assurance about the physician is that he possesses requisite skills in the branch of the profession, and while undertaking the performance of his task, he would exercise his skills with reasonable competence. Further, a liability would only come, if (a) either the person (doctor) did not possess the requisite skills, which he professed to have possessed; or (b) he did not exercise, the skill which he did possess with reasonable competence in a given case. Additionally, its not necessary for every professional to possess the highest level of expertise in that branch in which he practices. It also quotes from Halsbury's Laws of England: "To establish liability on that basis it must be shown (1) that there is a usual and normal practice; (2) that the defendant has not adopted it; and (3) that the course in fact adopted is one no professional man of ordinary skill would have taken had he been acting with ordinary care."

IS WRONG DIAGNOSIS CONSIDERED AS MEDICAL NEGLIGENCE?

- A wrong diagnosis on its own is not necessarily medical negligence, and not all diagnostic errors give rise to a successful lawsuit.
- A case of misdiagnosis may involve, a wrong diagnosis, or a missed diagnosis, or a delayed diagnosis, or a failure to recognize complications that change or aggravate with the existing condition. Sometimes, a doctor may diagnose one condition correctly, however, may miss the concomitant condition or may fail to realize that there is a second diagnosis that needs to be made.
- Additionally, a wrong diagnosis may be considered as medical negligence if it can be proven that the physician failed to provide an assessment that a reasonably competent doctor would have provided. However, the burden of proof falls on the patient in these cases.
- For a wrong diagnosis or misdiagnosis to be actionable, there should be improper medical care, delayed treatment, or no treatment, which in turn must result in a worsening of the patient's medical condition; for the malpractice to be actionable. It must be proved that the diagnostic error caused harm to the patient.
- In **Kusum Sharma and others vs Batra Hospital and Medical Research Centre and others**[1], it was held that a medical practitioner would be liable only where his conduct fell below that of the standard of a reasonably competent practitioner in his field. However, there is a scope of difference of opinion, and, merely a difference in conclusion from other professional doctors, will not make him negligent.

WRONG DIAGNOSIS NOT HELD AS MEDICAL NEGLIGENCE

- In **Vinod Jain vs Santokba Durlabhji Memorial Hospital and another**,[4] the Supreme Court dismissed an appeal against the order of the National Consumer Disputes Redressal Commission. The Commission had dismissed the complaint alleging medical negligence on the part of a hospital in the death of his wife. The NCDRC had held that the case "would at best be a case of the wrong diagnosis, but not medical negligence".
- In **Kamani Sharma vs Pamposh Medical Care Centre**,[5] complainant Ms. Kamani filed a complaint against the doctor of Pamposh Medical Care Centre for the wrong diagnosis as they diagnosed a case of tuberculosis which was later found in the Rajiv Gandhi Cancer Hospital and Sir Ganga Ram Hospital to a case of advanced lung cancer. The complainant (patient's wife) argued that there was a wrong diagnosis made by the doctor at Pamposh Medical Care Centre where the patient's condition became critical and he died within a short period and she claimed compensation of Rs 65 lakh for the deficiency in service. The bench dismissed the petition mentioning that it was a case of 'error of judgment' and not medical judgment. The commission ruled that it is a case of error of judgment where the physician failed to diagnose it as cancer at the initial period of examination and there was negligence on the part of the patient since he never approached the doctor for 8 months for which the doctor cannot be made liable.

WRONG DIAGNOSIS HELD AS MEDICAL NEGLIGENCE

Ayesha Begum vs All India Institute of Medical Sciences, New Delhi[6] **(Complaint No. 155/2000):** The complainant sought compensation of Rs 19 lakh with interest @ 18% on account of opposite parties, the institute and doctors, having wrongly diagnosed her as a case of breast cancer followed by surgical removal of her right breast.

Facts of the Case

- Complainant, a 50-year-old lady, noticed a lump in her right breast. She underwent Fine Needle Aspiration Cytology (FNAC) at Dayal Clinic, Bareilly. The histopathological examination of the sample drawn from her right breast nodule was done by the doctors at Dayal Clinic, Bareilly and a report showing suspicion of malignancy was provided to the patient. For confirmation, the complainant obtained the slide and proceeded for further examination to the OP, AIIMS, New Delhi. The OP examined the slide deposited by the complainant and opined further evidence is needed to confirm cancer. The OP had insisted that they would draw their own FNAC sample from the body of the complainant. The complainant accordingly paid the requisite fee and another sample was drawn by the OP. The OP based upon the examination of the slide prepared by the OP gave the opinion diagnostic for cancer.
- Upon the FNAC test report, the complainant was advised admission and surgery. The complainant was admitted to the Surgical Oncology Ward, IRCH, AIIMS, and was operated upon. The right breast was surgically partially removed along with the lymph nodes.

- The histopathology report generated by the OP indicated that the lump removed from the complainant's body was not cancerous. Radiotherapy was administered by the OP to the complainant even before the discharge of the complainant and as postoperative treatment.
- The histopathology report referred to as Annexure C-8 stated that one more test was forthcoming, namely the hormone receptor study clinical history. The OPs never made available the result of the said test to the complainant probably because the said test indicated no cancer and would have, therefore, exposed the deficiency in service on the part of the OP. A perusal of the said report showed the finding consistent with benign phylloides tumor. On reading the same, the complainant decided to take further opinion of other competent medical professionals to ascertain whether the complainant had ever suffered from cancer at all.
- Based on this position, the complainant alleged that the appellant/opposite parties committed negligence and deficiency in service in having wrongly diagnosed the complainant to be suffering from breast cancer (well-differentiated adenocarcinoma) and not only removing her right breast (which was not required to be removed) but also having made her undergo entirely unnecessary radiotherapy treatment, detrimental to her health.

The State Commission's Decision

- The State Commission held that, on the face of it, it is a case of the wrong diagnosis as in the biopsy report dated 23-06-1998, absence of cancer has been mentioned. To say that the FNAC slides might have sampled the area only which was not having bare nuclei and not having myoepithelial cells is not available as the OP also subjected the complainant to the fresh exercise of FNAC on 04-06-1998 and came to the conclusion that the lump in the right breast was cancer.
- Even the examination of initial FNAC slides at Bareilly as well as the OPs expert pathologists showed the absence of cancer. Thus, not only the diagnosis was wrong but the examination of the OP was not proper and correct. It was decided that its not only a case of error of judgment; it is a case of either negligence or incompetence of the OPs doctors to read the FNAC (fine needle aspiration cytology) properly as a result of which the complainant underwent surgery and radiotherapy and suffered immense pain, disfigurement of the body, etc. psychological impact of which is unfathomable. It added that, merely because the complainant consented, does not absolve the OPs from the charge of medical negligence. Here is a case where the wrong diagnosis led to the removal of a breast of a lady suffering of which is of such high magnitude which cannot be compensated in terms of money.
- The court added that considering the pitfalls in the procedure of detecting cancer by FNAC or histopathology, it can be said that the negligence of the OP was limited to the extent of the wrong diagnosis which resulted in very serious consequences such that the right breast and armpit of the complainant had been removed; she cannot walk, and has become disabled and has suffered disfigurement of the body. The court thinks that a lump sum compensation of Rs. 500,000 (five lakh), for the mental agony and trauma, emotional suffering, the disfigurement of her body causing immense lifelong loss of conjugal bliss, shall meet the ends of justice.

REFERENCES

1. Kusum Sharma and others vs Batra Hospital and Medical Research Centre and others (Civil Appeal No. 1385 of 2001). Available at: https://indiankanoon.org/doc/29738758.
2. Bolam vs Friern Hospital Management Committee (1957) 2 All ER 118. Available at: https://en.wikipedia.org/wiki/Bolam_v_Friern_Hospital_Management_Committee.
3. Jacob Mathew vs State of Punjab (2005) 6 SCC 1. Available at: https://indiankanoon.org/doc/871062.
4. Vinod Jain vs Santokba Durlabhji Memorial Hospital and another (Civil Appeal No. 2024 of 2019 Arising out of SLP(C) No.32721/2017, dated February 25, 2019) Available at: https://indiankanoon.org/doc/170787422.
5. Ms. Kamani Sharma and others vs Dr. Anil Nadir and others. Consumer Case No. 351 of 2001, National Consumer Disputes Redressal Commission, 2015. Available at: http://cms.nic. in/ncdrcusers Web/Get Judgement.do?method= GetJudgement&caseidin=0%2F0%2 FOP%2 F351%2F2001& dtofhearing= 2015-07-13.
6. Ayesha Begum vs All India Institute of Medical Sciences, New Delhi. Complaint No. 155/2000. Available at: https://indiankanoon.org/doc/9398095.

Chapter

30

Error, Imperfection and Unexpected Outcome

Chandrika Rao

INTRODUCTION

Patients in India are increasingly growing aware of medical negligence. The number of complaints in hospitals about patient facilities, physician professionalism, and prescription errors, need for certain diagnostic investigations are increasing. Studies point to more than 52 lakh medical injuries every year in India. Of that fatalities in 98,000 people in the country are because of medical negligence. Medical community should address the issue that 10 people fall victim to medical negligence every minute and more than 11 people die every hour in the country due to medical error.[1]

Definitions

Negligence: It is a failure to exercise appropriate and or ethical care, normally expected to be exercised amongst specified circumstances. The core concept of negligence is that doctors should exercise reasonable care in their actions, by taking account of the potential harm that they might foreseeably cause to patients.[2]

Criminal negligence: This occurs when a doctor treats or acts in a way that is an extreme departure from the way that a "reasonable" person would have treated or acted in the same or similar situation. Criminal negligence generally involves an indifference or disregard for human life or for the safety of other individuals.[3]

Some of the common categories of medical negligence are as follows:

1. Delay in diagnosis: This is labelled as negligence when it would have otherwise been diagnosed earlier.
2. Error in surgery: Performing surgery on wrong limb or leaving any foreign object in the body of the patient such as a sponge or bandage, etc. after the surgery.
3. Errors in the administration of anesthesia: Prior to any medical procedure requiring anesthesia, the anesthesiologist has to review the patient's condition, history, medications, etc. to determine the most suitable of all the medicine to use.
4. Childbirth and labor malpractice: Doctor may not be present or delayed a decision to give medications.
5. Long-term negligent treatment: Medical negligence can be a failure to follow up with treatment, or a doctor's failure to monitor the effects of the treatment properly.

What is Deficiency of Service?

Deficiency of service means any fault, imperfection, shortcoming, or inadequacy in the quality, nature, or manner of performance that is required to be maintained by or under any law for the time being in force or has been undertaken to be performed by a person in pursuance of a contract or otherwise in relation to any service.

In order to prove medical negligence under the negligence rule, it is important that the patient must be able to establish that:

a. The doctor owed him a duty of care of a particular standard.
b. The doctor contravened the duty.
c. The patient suffered damage.
d. The doctor's conduct was the direct cause of damage.

Duties of a doctor in care to patients includes the following:

- It is his duty to decide whether he wants to undertake the case or not.
- It is his duty to decide what treatment to give.
- It is his duty to decide the administration of treatment.

When the above mentioned duties are not performed, breach of duty is said to have occurred. This happens when a doctor does not perform the degree of care like a reasonable doctor.

Adverse event: An undesirable and unintended result of a medical treatment or intervention.

A doctor is not responsible for the breach in all cases where a patient has suffered an injury. He/she might have a valid defense that he/she has not breached the duty of care.[4]

The error of judgment can be of two types:

- **An error of judgment:** There is consensus that it does not amount to a breach of duty. It is a recognition in law of the human fallibility in all spheres of life.
- **The error of judgment due to negligence:** If all the factors were considered before coming to a decision then it would be called an error of judgment due to negligence. This amounts to a breach of duty.

Unexpected outcome: Even though doctors, nurses, and health care facilities work hard to give patients the best care possible, patients can occasionally be injured during medical treatment. Sometimes an injury is a result of an error:

Medical error: An unintended healthcare outcome caused by a defect in the delivery of care to a patient or a preventable adverse event.[5]

They can be classified as:

1. Errors of commission (doing the wrong thing)
2. Errors of omission (not doing the right thing)
3. Errors of execution (doing the right thing incorrectly).

Errors in medical field result in harm to the patient.[6]

They include:

a. Diagnostic errors: Errors in diagnosis
b. Medication errors: Errors in the administration of drugs and other medications
c. Errors in the performance of surgical procedures
d. Errors in the use of other types of therapy

e. Errors in the use of equipment
f. Errors in the interpretation of laboratory findings.

Medical errors should be differentiated from malpractice[7] in that medical errors are regarded as honest mistakes or accidents while malpractice is the result of negligence, reprehensible ignorance, or criminal intent.

Degree of Negligence

There are three degrees of negligence:

1. Lata culpa, gross neglect
2. Levis culpa, ordinary neglect
3. Levissima culpa, slight neglect.

The court dictates that the following principles must be heeded to decide whether the concerned medical professional is guilty of medical negligence.[8]

1. Negligence is the breach of a duty exercised by omission to do something which a reasonable man would not do.
2. The negligence is an essential component and must be gross and should not be the negligence based upon the error of judgment.
3. The medical professional is expected to demonstrate skill and knowledge and a reasonable degree of care.
4. Liability of a medical practitioner would be when his conduct fell below that of the standards of a reasonably competent practitioner in his field.
5. There may be difference of opinions among medical professionals.
   Hence, negligence may not be established merely because his/her conclusion differs from that of the other professional doctor.
6. The medical professional may adopt a procedure which has a higher element of risk, but which may be more successful for the patient rather than a procedure involving lesser risk but higher chances of failure. Negligence cannot be established on the fact the professional who took higher element of risk to treat a patient out of his/her suffering could not obtain the desired result.
7. As long as a doctor performs his/her duties with reasonable skill and competence, acceptable to the medical profession, negligence cannot be attributed to the doctor.
8. Medical professionals should not be unnecessarily harassed or humiliated in order that they perform their professional duties without fear and apprehension.
9. The interest and welfare of the patients have to be paramount for the medical professionals.

Legal Avenues

In India, there are different legal options available to an aggrieved patient to sue a doctor. The legal framework of Indian law effecting the medical profession and to prevent malpractice is as follows.

Fundamental rights (Part III of the Indian Constitution)

1. Article 211.
2. Article 322: Directive Principles of State Policy (Part IV of the Indian Constitution).

3. Article 473: Indian Penal Code 2 (IPC 2) Section 523.2, Section 803.3, Section 813.
4. Section 883.5, Section 903.6, Section 923.7, Section 304-A3.8, Section 337 3.9, Section 3384, Indian Medical Council Act.
5. Consumer Protection Act (CPA)
6. Public Interest Litigation (PIL)
7. The Indian Penal Code—stated as in the IPC.

Provisions:

- According to Section 304-A of the Indian Penal Code, 1860, if a person commits a rash or negligent Act which amounts to culpable homicide then the person will be punished with imprisonment for a term which may extend to two years or with fine or both.
- According to Section 337 of the Indian Penal Code, 1860, if a person commits a rash or negligent Act due to which human life or personal safety of others gets threatened. The person will be punished with imprisonment for a term which may extend to six months or with fine which may extend to five hundred rupees or both.
- According to Section 338 of the Indian Penal Code, 1860, if a person commits a rash or negligent Act due to which human life or personal safety of others gets threatened. The person will be punished with imprisonment for a term which may extend to two years or with fine which may extend to one thousand rupees or both.

Defences:

- Section 80 of the Indian Penal Code, 1860, says that anything which happens as a result of an accident or misfortune and without any criminal intention or knowledge in the doing of a lawful act in a lawful manner by lawful means and with proper care and caution is not an offence.
- Section 81 of the Indian Penal Code, 1860, states that if anything is done merely by the reason that it is likely to cause harm but if the same is done without any intention to cause harm and in good faith in order to avoid other damages to a person or his property is not an offence.
- Section 88 of the Indian Penal Code, 1860, says that no one can be made an accused of any offense if he performs an Act in good faith for the good of other people and does not intend to cause harm even if there is a risk involved and the patient has given the consent explicitly or implicitly.
- Section 52: "Good faith": Nothing is said to be done or believed in "good faith" which is done or believed without due care and attention, not intended to cause death, done by consent in good faith for person's benefit":
- Section 90: 'Consent known to be given under fear or misconception'
- Section 92: "Act done in good faith for benefit of a person without consent": Nothing is an offence by reason of any harm which it may cause to a person for whose benefit it is done in good faith, even without that person's consent, if the circumstances are such.

The Indian Medical Council Act (IMC Act), 1956 confers powers to the Medical Council of India to discipline erring members of the medical profession. However, this Act does not have any provision for the award of damages to the complainant,

though it has enough, powers to punish the medical practitioners. Section 24 of the Act, empowers the council to remove the name of any person enrolled on a state medical register on the grounds of professional misconduct.

The Consumer Protection Act: The doctor–patient relationship is a 'contract for personal service' and hence comes under the CPA.

Public interest litigation (PIL):Any person can directly approach the High Court or the Supreme Court by filing a PIL when any grievances affecting the public at large are not properly redressed. PILs are usually resorted to when public health program are not implemented properly.

'*Res ispa loquitur*' means "the thing speaks for itself". It is applicable in cases where the accident could not have happened without negligence and the circumstances conclusively show that the doctor and not any other person were negligent. In such circumstances no proof of negligence is required beyond the accident itself. In that case the plaintiff will get 100% of the damage as compensation. Some common scenarios of *res ipsa loquitur* cases are given below:

- Leaving some object inside the body of the patient after surgery.
- If a wrong patient gets operated.
- If the wrong part of the patient gets operated.

Steps Taken in a Case of Medical Negligence[9]

- A complaint is an allegation made by a complainant, in written form. It consists of the facts to establish a case that a consumer has suffered loss or damage due to deficiency of any service. It must be filed by the patient party with the local police, civil, consumer court and the State Medical Council.
- A minimal fee is required for filing a complaint before the district consumer forum.
- If it is filed only with the police, then the police can send the report to the State Medical Council. If the report seems appropriate to the council then it will send it to various other courts under the relevant sections. If the case is criminal in nature then it will be the state versus the hospital or doctor.
- When a complaint against medical negligence is filed, the forum sends a notice to the opposite party to submit its version of the case within 30 days. After proper scrutiny the forum will ask either for filing an affidavit or for producing evidence in the form of judicial precedents, expert opinion, etc.
- The doctors may inform police whenever necessary and should extend all possible co-operation to the police.
- The doctors should preserve the documents, records specially in medicolegal, controversial or complicated cases. It is important to properly maintain case history, clinical records, affidavit of all the treating doctors, X-rays, laboratory test results, etc. which will be of immense help in supporting the doctor's claim.
- The doctor should also furnish copies of medical records to police, court or relatives whenever demanded. Consent of patient may be taken while providing information to police.
- The doctors should have a valid informed consent for the treatment.
- The doctor should insist for postmortem examination if the cause of death cannot be ascertained.

- The doctors can involve medical associations, medicolegal cells, voluntary organizations whenever legal problem arises.
- The doctors should consult the lawyer before giving any reply and should not panic. The doctor and/or hospital are entitled to engage the services of a lawyer to represent them in the matter.
- The doctors should not tamper with the documents. As per the guidelines of the Medical Council of India, the patient should get all the medical records within 72 hours from the date and time of the application.
- The doctors should not neglect the treatment while completing legal formalities, especially in serious or emergency situation.
- If the council finds that the case is serious and pose a danger to the life of the patient, then it can also suspend the doctor's license for a relevant period of time.
- If the council finds a doctor guilty, the facts and circumstances of the case will decide the punishment to be given to the doctor.
- If the patient is still not satisfied with the judgment then he/she can make an appeal to the Medical Council of India.
- The consumer courts can help the patient in seeking monetary compensation. It should be noted that the consumer courts can only provide the compensation. It cannot punish the guilty.
- If the complainant is still not satisfied then he can approach the National Consumer Dispute Redressal Commission.

Medical Malpractice Insurance

Every medical practitioner should have a liability insurance known as 'Professional Liability/Indemnity Insurance', which covers negligent malpractice resulting in an injury of a patient. Malpractice insurance protects the physician against the financial catastrophe that could result from even a single case against him.

Burden of Proof

The burden of proof of negligence generally lies with the complainant. In cases of medical negligence, the patient must establish a claim against the doctor in order to succeed.

Medical Negligence Complaint in Civil Cases

- Under the tort law or civil law, medical negligence is applicable even if doctors provide free services. The tort law begins when the Consumer Protection Act (CPA) ends.
- It implies that patients can claim compensation under the tort law when the services do not fall within the CPA definition.
- The burden of proof is on the patient and he needs to prove that because of the doctor's actions, the injury has been caused to him.

Compensation claim: In civil liability, the claim for damages is suffered in the form of compensation, if there is any breach of the duty of care while operating or under the supervision of the hospital or any doctor. They are vicariously liable for such wrong committed and are liable to pay damages in the form of compensation.

If someone is an employee in a hospital then it is the responsibility of the hospital if an employee causes harm to a patient by acting negligently.

Citations or Present Case Laws Decided by Competent Authorities like Medical Councils/Consumer Courts/Other Courts, etc.

1. In **A.S. Mittal vs State of UP**, AIR 1989 SC 1570 an irreparable damage was done to the eyes of some of the patients who were operated at an eye camp organized by the government of Uttar Pradesh. The apex court coming heavily on the erring doctors held that, "the law recognizes the dangers which are inherent in surgical operations and that will occur on occasions despite the exercise of reasonable skill and care but a mistake by a medical practitioner which no reasonably competent and a careful practitioner would have committed is a negligent one." The compensation was awarded.
2. The apex court in **Jacob Mathew vs State of Punjab**, has explained that; "the expression" rash and negligent Act occurring in Section 304-A of the IPC should be qualified by the word grossly. To prosecute a medical professional for negligence under criminal law it must be shown that the accused did something or failed to do something which in the given facts and circumstances no medical professional in his ordinary senses and prudence would have done or failed to do.
3. In **Poonam Verma vs Ashwin Patel**, the Supreme Court distinguished between negligence, rashness, and recklessness. A negligent person is one who inadvertently commits an Act of omission and violates a positive duty. A person who is rash knows the consequences but foolishly thinks that they will not occur as a result of her/his Act. A reckless person knows the consequences but does not care whether or not they result from her/his Act. Any conduct falling short of recklessness and deliberate wrongdoing should not be the subject of criminal liability.

   Thus, a doctor cannot be held criminally responsible for a patient's death unless it is shown that she/he was negligent or incompetent, with such disregard for the life and safety of his patient that it amounted to a crime against the state.
4. Before the case of **Jacob Mathew vs State of Punjab**, the Supreme Court of India delivered two different opinions on doctors' liability. In **Mohanan vs Prabha G Nair** and another, it ruled that a doctor's negligence could be ascertained only by scanning the material and expert evidence that might be presented during a trial.
5. Medical practitioners could be held liable under civil and criminal negligence both till 2005. A landmark verdict in this regard was that of **Dr Suresh Gupta vs Government of NCT of Delhi**. In Suresh Gupta's case in August 2004 the standard of negligence that had to be proved to fix a doctor's or surgeon's criminal liability was set at "gross negligence" or "recklessness.". The Supreme Court distinguished between an error of judgment and culpable negligence. It is held that criminal prosecution of doctors without adequate medical opinion pointing to their guilt would do great disservice to the community. A doctor cannot be tried for culpable or criminal negligence in all cases of medical mishaps or misfortunes. Supreme Court thus ruled that doctors should not be held criminally responsible unless there is prime facie evidence before the court in the form of a credible

opinion from another competent doctor, preferably a government doctor in the same field of medicine supporting the charges of a rash and negligent Act.

6. A Public Interest Litigation was filed in August, 2008 by **Dr Kunal Saha at Delhi High Court against the National AIDS Control Organization** (NACO) for their devious role with sub-standard HIV kits that were used in different Indian hospitals/blood banks during the second national AIDS control project between 1999 and 2006. The court issued notices after hearing the public interest litigation, seeking a CBI investigation of the defective HIV kits being used, which were potentially endangering transmission of the deadly AIDS virus to innocent patients through contaminated blood transfusion.
7. In **Kusum Sharma vs Batra Hospital**, it was held by the Supreme Court that a doctor often adopts a procedure which involves a higher element of risk, but in doing so he honestly believes that it will provide greater chances of success for the patient. If a doctor has taken a higher risk to redeem the patient out of his/her suffering and it did not yield the desired result, this may not amount to medical negligence.
8. In **Jasbir Kaur vs State of Punjab**, a newly born child was found missing from the bed in a hospital. The child was found bleeding and near the wash-basin of the bathroom. The hospital authorities argued that the child had been taken away by a cat which caused the damage to him. The court held that the hospital authorities were negligent and had not taken due care and precaution. Thus, awarded the compensation amounting to Rs 1 lakh.
9. In **Mr M Ramesh Reddy vs State of Andhra Pradesh**, the hospital authorities were held to be negligent for not keeping the bathroom clean due to which an obstetrics patient fell in the bathroom and died therein. The amount of compensation which was awarded against the hospital was Rs 1 lakh.
10. **Dr Kunal Saha Represented By Sri … vs Dr. Sukumar Mukherjee and others**, is famous as the Anuradha Saha case. In this case, the wife was suffering from drug allergy. The doctors were negligent in prescribing appropriate medicines which aggravated her condition and led to the death of the patient. The court held the doctor liable for medical negligence and awarded compensation amounting to Rs 6.08 crore.
11. In the case of **V. Kishan Rao vs Nikhil Super Speciality Hospital**, a lady was treated for typhoid instead of malaria. Her husband was an officer in the malaria department and filed a suit against the hospital authorities for performing the treatment of his wife negligently. The husband got the compensation of Rs 2 lakhs and in this case, the principle of *res ipsa loquitur* was applied.
12. In **Spring Meadows Hospital and another vs Harjol Ahluwalia**, a child who was suffering from typhoid was admitted to the appellant's hospital. The child collapsed after an injection. After taking all the possible steps the child was shifted to AIIMS. The doctors there informed the parents about the critical condition of the child. The child had a cardiac arrest because of the overdose injection that was given to him. The court held the doctor and the nurse liable to compensate for this negligence.

CONCLUSION

People see 'God' in doctors who cure the sick patients. Occasionally, even the doctors make mistakes which impact the patient adversely. In some instances the mistakes made by them can cause fatality.

Doctors need to be competent and uphold the medical ethics. They also need to take steps to learnt the medicolegal aspects and ensure correct documentation, maintain good medical records, practice good communication.

REFERENCES

1. https://www.indiamedicaltimes.com/2016/05/25/98000-people-lose-their-lives-because-of-medical-negligence.
2. "Negligence". Oxford Living Dictionaries. Oxford University Press. Retrieved 24 July 2017. "Negligence". Encyclopædia Britannica. Merriam Webster.
3. Criminal negligence Dictionary Definition : Vocabulary. com, https://www.vocabulary.com.
4. Makary, Martin A; Daniel, Michael. "Medical error—the third leading cause of death in the US". *BMJ* May 3, 2016;353: i2139.)
5. Hayward, Rodney A.; Hofer, Timothy P. (July 25, 2001). "Estimating Hospital Deaths due to Medical Errors: Preventability is in the Eye of the Reviewer". *JAMA* July 25, 2001;286 (4): 415–20.
6. Maskell, Giles (2019). "Error in radiology—where are we now?". *The British Journal of Radiology*. 92 (1096): 20180845.
7. Brock DM, Nicholson JG, Hooker RS. "Physician Assistant and Nurse Practitioner Malpractice Trends". *Medical Care Research and Review* October 2017;74 (5): 613–24. doi:10.1177/1077558716659022. PMID 27457425.
8. Owen, David G. "The Five Elements of Negligence". Hofstra Law Review, Summer 2007; 35(4): 1671.
9. Pandit MS, Pandit S. Medical negligence: Criminal prosecution of medical professionals, importance of medical evidence: Some guidelines for medical practitioners. *Indian J Urol* 2009 Jul;25(3):379–83. doi: 10.4103/0970-1591.56207. PMID: 19881135; PMCID: PMC2779964.

Chapter
31

Informed Consent: Is it Must?

Piyali Bhattacharya

Patient safety is a major focus in health care with four pillars of ethical healthcare practice, viz.

1. Respect for **autonomy:** The patient has a right to refuse or choose treatment.
2. **Beneficence:** A practitioner should act in the best interest of the patient.
3. **Non-maleficence:** To not be the cause of harm
4. **Justice:** Concerns the distribution of scarce health resources, and the decision of who gets what treatment.

Informed consent is now accepted as the cornerstone of medical practice.[1] Adequate informed consent is rooted in respecting a person's dignity. In India, the common law doctrine is not fully developed and courts seek Indian Contract Act and Indian Penal Code for cases falling in gambit of consent. Section 13 of the Indian Contract Act lays down that two or more persons are said to consent when they agree upon the same thing in the same sense (meeting of the minds).

The concept and scope of informed consent has been one of the most highly debated issues in medical treatment in India. The first Indian case that emphasized the importance of informed consent was *Ram Bihari Lal vs Dr JN Srivastava*.[2]

A patient suspected to have appendicitis was operated upon after taking her consent for appendisectomy. During operation the appendix was found to be normal but the gall bladder was gangrenous. The doctor removed the gall bladder and was held liable for operating without consent. It was held that the doctor acted as per traditional paternalistic notion and decided on behalf of the patient himself. Unfortunately, the law does not accept this notion.

Medical Council of India in its Regulations, 2002[3] has held that a physician should obtain in writing the consent from the patient himself or husband/wife, parent or guardian in the case of minor, as the case may be before performing an operation. Otherwise, it shall constitute professional misconduct by the physician making him/her liable for disciplinary action by MCI.

WHAT IS INFORMED CONSENT?

Definition: It can be defined as "the voluntary and revocable agreement of a competent individual to participate in a therapeutic or research procedure, based on an adequate understanding of its nature, purpose and implications."[4]

According to the Supreme Court in *Samira Kohli vs Dr Prabha Manchanda and another (2008) 2 SCC1*[5] consent in the context of a doctor–patient relationship, has been defined as the grant of permission by a patient for an Act to be carried out by a doctor, such as a diagnostic, surgical or therapeutic procedure.

Informed consent is therefore the process of communication between a patient and physician followed by the patient's authorization or agreement to undergo a specific medical intervention.

Informed consent is also a mandatory requirement for research and clinical trials. A volunteer has the right to know and understand what happens during the course of the clinical trial prior to participation. Having been informed of all relevant aspects of the trial, he is free to make a voluntary decision regarding participation in the said clinical trial.

The Supreme Court in *Samira Kohli (supra) has* discussed the following elements of informed consent: Disclosure, capacity and voluntariness.

a. The doctor must **disclose** all information on the treatment, test, or procedure in question with the expected benefits and risks, and their probability of occurrence. Disclosure must ensure that the subject adequately understands the information provided.
b. Subject must have the **capacity** (or ability) to make the decision. Decision-making capacity, or competency, means that one can understand the options, their implications, and give a rational reason for deciding on a particular option instead of another available alternative.

The Supreme Court in *Samira Kohli (supra)* has held that performance of such a surgery was an unauthorized invasion and interference with the patient's body which amounted to a tort Act of assault and battery and therefore, a deficiency in service under the Consumer Protection Act, 1986.

According to the law of tort—battery is defined as 'application of force to the person of another without lawful justification'. Therefore in absence of proper consent battery would be committed.[6]

Why do we Need Informed Consent?

Informed consent is required for the following reasons:

- It provides for greater patient safety and satisfaction.
- Attainment of higher ethical standards and organizational morale.
- Closer adherence to legal requirements and reduced risk of litigation.
- Increased levels of institutional quality (e.g. compliance with accreditation standards).
- Potential time and money savings related to reduced litigation.

Who can give Valid Informed Consent?

A person who is an adult and mentally competent or his legally authorized representative or legal guardian can give informed consent. In the absence of a legal 'Power of Attorney', a "statutory surrogate" is allowed to give consent. Statutory surrogates include the patient's spouse (unless legally separated), adult child of the patient (if more than one child, consent of available majority), parent of the patient, brother or

sister of patient or a close friend of patient who is familiar with the patient's health care and desires to act in the patient's best interest.

Indian Contract Act, 1872: Every person is competent to contract who is of the age of majority according to the law to which he is subject and who is of sound mind, and is not disqualified from contracting by any law to which he is subject.

The Indian Majority Act, 1875: The legal age for giving a competent consent in India is 18 years as per the Indian Majority Act. Whereas in children between 12 and 18 years consent for physical examination and treatment.

Situations wherein Consent is not Valid

As per Section 90 of IPC, if any consent given under the following circumstances will not be true consent:

1. By a person under fear of injury.
2. By a person who is under misconception of the facts and person who obtain consent knows or has reason to believe that or consent was given inconsequence of such fear/misconception.
3. By intoxicated person.
4. By a person who is of unsound mind or, unable to understand the nature and consequences of that to which he gives consent.
5. By a person who is below the age of 18 years.

Informed Consent for Medical Procedures

The clinician must explain to the patient all factors pertaining to the procedure to be performed, viz.

1. The probable diagnosis
2. The nature, purpose, risks and benefits of a proposed procedure
3. Alternatives and their risk and benefits
4. The risks and benefits of not receiving treatments or undergoing procedures.

In *Canterbury vs Spence*,[7] the US court emphasized on patient's right to know all material risks and the obligation of doctor to disclose the risks associated with treatment. In this particular case, the risk of paralysis after spinal surgery was not discussed while taking consent. Such failure on the part of doctor amounts to negligence.

'Informed consent', should be explained verbally in the patient's native language as far as possible but can be written in legible English. Medical jargon should be restricted to make sure that the patient understands what he has to undergo. The process must allow time for any questions or queries that may arise from the patient's end.[8]

Sometimes language assistance through an interpreter may be required. If translation services are used, the interpreter must sign as a "witness" with their name, title, date and time. Finally, the patient (or statutory surrogate) should sign the consent along with two persons who witness the patient's signature.

Some Special Considerations

a. Children do not have the decision-making capacity to provide informed consent. Therefore, treatment of children is mainly under the consent of parent or guardian

or under the doctrine of *loco parentis*, where the consent is given by a third party in place of patient.[4]

Parents or other surrogate decision-makers may give informed permission for diagnosis and treatment of a child, preferably with the 'assent' of the child whenever possible. Assent means "A child's affirmative agreement to be a participant in research. Verbal assent is allowed for a child aged 7–12 years while a written 'assent' is required for children 13–17 years.

Once the parent has been given all required information; a separate consent form should be completed with the guardian's signature and date clearly stating his or her relation to the child.

In case of an emergency, where the child is away from home and the parents or guardian are not available, consent can be taken from person in charge, e.g. principal of a residential school or a teacher at the school picnic, etc.

b. In case of an illiterate person, the risks and benefits of the study are explained verbally. The subject indicates approval or disapproval for study enrollment by placing a written mark, e.g. thumb impression on the consent form.
c. **Sedated patient:** Consent forms should be preferably signed by a patient prior to sedation. If the patient is already sedated it can be signed by the patient's nearest relative, such as his spouse or parent when the name and relationship must be clearly documented.
d. **Obtaining consent for only one procedure:** The consent given for a specific treatment procedure will not be considered valid for conducting some other treatment procedure. When a second procedure may be needed which may bring about additional information that makes it necessary to do an additional procedure, the second procedure cannot be performed without taking consent again. The correctness or appropriateness of the treatment procedure, in the absence of consent for the treatment does not make the treatment legal.

   This principle has been reiterated by the Supreme Court in *Nizam's Institute of Medical Sciences vs Prasanth S. Dhananka and others (2009) 6 SCC 1.*

   It was pleaded that the consent that had been taken was only for the purpose of an excision biopsy which was an exploratory procedure, but the doctor had carried out a complete excision removing the tumour mass and the fourth rib thereby destroying the inter-costal blood vessels leading to paraplegia.

   It was further alleged that the complications which could possibly flow as the result of an excision biopsy had not been spelt out to the complainant prior to the procedure. It was also submitted that operating on a neurofibroma or a schwannoma which had neurological implications as well, warranted the involvement of a neurosurgeon but no such opinion was sought before the surgery. Had a neurosurgeon been associated with the operation, this problem could well have been avoided. Doing the procedure without explicit consent exposed the doctor, and the hospital to serious liability issues.
e. In assisted reproductive technologies that include fertilization involving manipulation of gametes outside the human body and the transfer of gametes or embryos into the body, informed consent should be taken from the spouses as well as the donor, as the case may be, for possible side effects, and the risk of treatment. As per the Delhi Artificial Insemination Act, 1995, written consent of both husband

and wife seeking artificial insemination and also consent for single screen semen for HIV through enzyme-linked immunosorbent assay (ELISA) should be taken.

For contraceptive sterilization, consent of both husband and wife should be obtained as abundant precaution though not required by law.

Research and Informed Consent

The Indian Council of Medical Research in its guidelines (Clause 7.22) clearly states that any research or drug trial where there is patient or volunteer contact needs consent with ethical considerations kept in mind. Consent taken from the patient for trial of drug or therapy, which is not as per the guidelines, shall also be construed as misconduct.

A valid consent form for a clinical trial must be:

a. Written in plain language that any reasonable patient can understand.
b. Must inform the patient that his information may be used for treatment, payment, or future care.
c. Must inform the patient of his right to review the form before signing.
d. Must indicate the patient's right to request restrictions on release of his health information.
e. Must inform the patient he has a right to revoke the consent in writing, but that actions taken prior to the signing are not subject to revocation.
f. It must include the patient's signature and date.

The consent form has a:

1. Protocol number/name of study.
2. Column for purpose and duration of study and subject involvement.
3. Statement that risks and benefits of the study was reviewed with the participant.
4. Alternative treatment options discussed.
5. Confidentiality record.
6. Compensation for injury that may occur during the study.
7. Time for questions to be asked and answered.
8. Participant's decision.
9. Contact details.
10. Travel re-imbursement.
11. Subject responsibilities.
12. Subject satisfaction.
13. Use of understandable language.
14. Signed and dated copy of ICF must be given to the participant.

The participant needs to be informed that he has the right to leave the study at any time, and that standard medical care will be provided even then. Although an informed consent document is signed before enrollment in a study, it is important to remember that informed consent is a process that continues throughout the study.

Unlike medical procedures, an impartial witness may be required in certain cases of research trials. An *impartial witness* is defined as a person who is independent of the trial, who cannot be unfairly influenced by people involved in the trial and who attends the informed consent process.

Revisions to Informed Consent

Informed consent documents must be revised every time there is a change in trial procedures or participant compensation. Revisions to the informed consent document must be approved by an Ethics Committee prior to its use. The new information and documentation has to be intimated to all participants in the trial and each and every participant must sign a revised consent form thereafter.

Situations where Informed Consent is not Required

Not every procedure requires explicit informed consent, e.g. taking blood pressure is a part of medical treatment but a discussion regarding the risks and benefits of using a sphygmomanometer is usually not required. There are specific situations where the medical practitioner is allowed to treat without obtaining an informed consent, e.g.

1. The patient is incapacitated due to injury or illness:
   - If the patient's ability to make decisions is questionable, an evaluation by a psychiatrist to determine competency should be requested.
   - When a patient cannot make decisions independently and has no designated decision maker, the hierarchy is determined by identifying a legal surrogate decision maker. If this is unsuccessful, a legal guardian may need to be appointed by the court.
   - Unconscious/unknown patient when admitted in hospital, the medical superintendent/in-charge of hospital can give consent for treatment.
2. Life-threatening emergencies with inadequate time to obtain consent, e.g. if the patient is unaccompanied. In case of medical emergency, failure to take consent from patient for treatment will not amount to battery and medical practitioner are provided immunity under Section 92 of IPC, 1860.

   In the case of *Dr T.T. Thomas vs Smt Elisa*[9] the question was the liability of a doctor for not performing an emergency operation for want of patient's consent and consequent death of patient.

   A patient with severe abdominal pain was diagnosed as appendicitis and hospitalized. On the next day his condition deteriorated fast and surgery could not have been performed on him. His cause of death was attributed to 'perforated appendix with peritonitis'. The mother, the widow and the children of the deceased or the plaintiffs filed this suit for damages, limiting their claim to half a lakh of rupees.

   The main contention of the appellant/surgeon, in his written statement, was that no surgery was done on the patient because of the reluctance of the patient to undergo a surgery saying that "he had similar attacks before and he used to get relief with injections and other medicine". However, there was no mention of consent refusal in case sheet of the patient. Kerala High Court held the doctor negligent for failure to perform emergency operation.

   The Indian Supreme Court reiterated in the *Paramanand Katara vs Union of India* case also that it is the doctor's ethical and legal duty to treat the patient to the best of his/her ability and that the lack of a valid consent is not a constraint in life-threatening situations.

3. In case the patient is a minor and parents cannot be reached. It needs special mention that even in emergency situations; only life-saving treatment is to be offered till proper consent is obtained later on.
4. Consent of ones spouse is not necessary for the treatment of other. Husband or wife has no right to refuse consent to any operation, which is required to safeguard the health of the partner.
5. Consent given for an illegal Act is not valid, e.g. criminal abortion. Doctor is punishable if he performs such an Act even with consent from the patient.
6. In case a pregnant woman is involved in a research project, the consent of the father must be taken into account. Waiver is allowed if:
   a. The purpose of the study is to meet the health needs of the mother.
   b. The identity or where about of the father cannot be reasonably ascertained.
7. A patient can withdraw consent while the procedure is being performed and the doctor is obliged to stop, unless, stopping the procedure puts the patient's life at risk and stop once that risk no longer exists. The procedure can only continue once the patient agrees after the concerns raised are addressed.
8. Waiver of the consent in a clinical trial may be applied where no foreseeable harm is expected to result from the study or when permitted by law, or if the ethical review committee has approved the non-disclosure of certain information.
9. Voluntary waived consent.
10. Statutory sections related to informed consent:
    Indian Penal Code, 1860, Section 53(1) of CrPC: In criminal cases when examination of an arrested person can lead to vital evidence related with the commission of crime, he can be examined by the doctor without his consent and even using force (by the police), if the application for examination is from a person not below the rank of sub-inspector.
    Section 90 of IPC: Consent given by an insane person or given under fear of injury, death, etc. or due to misconception of a fact is invalid.
    Section 92. Act done in good faith for benefit of a person without consent.

CONCLUSION

Informed consent is both an ethical and a legal obligation of medical practitioner. It not only safeguards the medical practitioner from litigation but also from considerable mental anguish and harassment. The core responsibility of taking an 'informed consent' rests mainly upon the clinician. However, a team approach is required with collaboration of the entire clinical staff, e.g. co-investigators, nurses and technical assistants, etc.

For an effective informed consent, the physician must disclose all relevant facts to the patient for decision making. He should answer queries truthfully, disclose success rates of the procedure and advise patients about health care staff involved in their care and their respective roles.

The IMC (Professional Conduct, Etiquette, and Ethics) Regulations, 2002[3] (4) states that every physician shall maintain the medical records pertaining to his/her indoor patients for 3 years from the date of commencement of the treatment. Failure to obtain an informed consent constitutes medical malpractice and renders a physician liable to medical negligence.

REFERENCES

1. Habiba MA; Examining consent within the patient–doctor relationship. *J of Med Ethics*, 2000; 26:183–87.
2. Ram Bihari Lal vs Dr J. N. Srivastava. AIR 1985 MP 150.
3. The Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002. *Issues Med Ethics* 2002;10:66–70.
4. Shaha N. The Importance of Informed Consent in Medicine. *Sch. J. App. Med. Sci.*, 2013; 1(5): 455–63.
5. Samira Kohli vs Dr Prabha Manchanda (2008) 2 SCC1:2008 ACJ 747:AIR 2008 SC1385:JT 2008(1)SC 399 (2008) 1 Scale 442.
6. Sareen R, Dutt A. Informed Consent in Medical Decision Making in India. *Journal of Counselling and Family Therapy* 2019;1(1):30–37.
7. Canterbury vs Spence, 464 F.2d 772, 782 (C.A.D.C. 1972).
8. Wear S. Informed consent: Patient autonomy and clinician beneficence within healthcare. 2nd Edition. Georgetown University Press, Washington DC, 1998.
9. Nandinath OV. Consent and medical treatment: The legal paradigm in India. *Indian J Urol* 2009;25:343–47.

Chapter
32

Medical Documentation

Padmakumar K

Medical records are documents prepared by health care worker which are maintained in the hospital during the course of treatment of a patient.[1] A medical record of a patient should be complete in all aspects and it shall contain patient details, reason for admission, provisional diagnosis, plan of care, final diagnosis, investigations done with results, care provided, procedure or surgery performed, any delay in performing procedure, tests or surgery and copy of discharge or referral. In case death occurs, a copy of death report or death certificate must also be documented. The progress notes must be included which reflects continuity of care. Medical record is relevant in following five situations.

1. **Medical records as a clinical data:** Medical records give details of care given to the patient.
2. **Medical records as a scientific data:** Data can be used for research and policy planning purposes.
3. **Medical records as an administrative data:** These documents can be used for evaluation of work efficiency of health care workers in the institution.[2]
4. **Proof of payment and insurance purpose:** Medical record is the only proof for expenses incurred while treating.
5. **Medical record as a legal document:** Medical record is the only evidence for the practitioner and the hospital to prove that treatment was carried out properly whenever litigation arises.

Precautions to be Taken while Documenting

a. Write medical records in legible handwriting.
b. Avoid overwriting, deletion, erasures, etc.
c. Record exact timing of important events, e.g. vomiting of blood.
d. Any instruction given to the patient should have a scientific justification.[3]
e. Record history, physical examination, diagnosis, investigations and the treatment advised in the chronological order.
f. Maintain copies of prescription orders, outpatient slips and investigation requests that are handed over to the patient.
g. Ensure that nurse's record is not inconsistent with doctor's notes.
h. Do not change from the usual style of documentation. Over documentation in selected case raises suspicion. Fabrication of medical records is a criminal offence and is punishable.

i. Always use the printed format if it is a part of institution policy. Do not leave blank spaces in a standardised printed format.
j. Use only common and accepted short forms or abbreviations.
k. Write names and put signature or initials at required places.
l. Maintain continuity in writing by using the space in existing paper before going to a new sheet of. Page number is also a suggestion.
m. Never prepare two discharge summaries and give to patient. [4]

In Medical Documentation Specifically Record

a. Failure of the patient to follow medical advice
b. Failure in follow-up visits.
c. Refusal of investigation.
d. Delay or deficiency from the part of the patient—for investigation, treatment, review.
e. Reason for starting a particular treatment or stopping the same.
f. Intimation of critical result after investigation.
g. During referring to another hospital: Date and transfer, reason for transfer, clinical condition before transfer, name and signature of the transferring doctor.
h. Delay in giving consent.
i. Any self-medication if reported.
j. Reason for doing a procedure or surgery as an emergency.
k. Reason for delay in performing a procedure.
l. Daily progress notes.
m. Vital parameters at regular intervals.
n. Diagnosis—provisional, differential or final.
o. Post-discharge advice in detail and in an understandable manner in the discharge card.

Consent and Documentation

Take consent only after proper counselling. The facts of counselling should be documented. Give time for decision making but document any delay for decision. Take consent on a day nearer to the day of surgery. Fill consent form by one person and by the same ink in single sitting. Mention the type of anesthesia and exact treatment procedure. Do not leave any blank column in the printed format. Write NA or not applicable if nothing to fill. Doctor should sign along with the patient.

If the decision taken in operation theatre is outside the purview of the consent taken from the patient, explain the condition to patient attendants and take their written consent. In case patient is a child, even though the consent of one parent is valid, it is ideal to take consent from both. Transfusion of blood must be done only after taking written informed consent. In case of planned or anticipated transfer, no consent is required for blood transfusion in emergency.

Custody of Medical Records

Many courts have observed that the original medical records are the property of the hospital and the patient has the property right for information present in the records. Thus, patient is entitled for a copy of the record. As per Section 1.3.2 of regulations of erstwhile Medical Council of India, a request for medical records by patient or

authorized attendant should be acknowledged and documents shall be issued within 72 hours.

It is the responsibility of the custodian to maintain the confidentiality and physical integrity of medical records in custody. Ensure that the medical records are prevented from any unauthorised use or disclosure.

Photography or photocopying of medical records by patient or patient attendants is a possibility in hospital. Care must be taken to prevent such attempts. If medical records are lost by theft, snatching or destruction by any person, inform police in writing.

Retention Period of Medical Records

A government of India memorandum specifically says that all medical records of indoor patients should be digitalised on regular and continuous basis and kept indefinitely for future reference as it contains valuable data. This data is for the use of research and policy planning purposes. Medical records, both outpatient and inpatients in hard copy form is to be stored for a period of three years. But the case sheets and registers of medicolegal cases may be stored for a period of ten years or till the disposal of cases related to these records.

The retention period of medical records varies from state to state as there are different regulations prescribed by different state governments. In Maharashtra, the retention period for outpatient case records is three years, for inpatient case records five years and for medicolegal records thirty years. In the state of Kerala for both outpatient and Inpatient case records the retention period is five years and for medicolegal records the period is fifteen years.

CONCLUSION

A medical record is an integral part of clinical practise and reflects the quality of care rendered by the practitioner as well as the hospital. At the same time medical record is the only proof for the doctor to justify management of his patient. The importance of medical records is correctly depicted in one court judgment which says;[5] medical record maintenance has evolved into a science of itself and form an important aspect of patient management. It will help the doctor to prove that the treatment was carried out properly. The proper medical record it will help them in the scientific evaluation of their patient profile, helping in analysing the treatment results, and to plan the treatment protocols. It is wise to remember that "poor records mean poor defence, no records mean no defence".[2,5] In the era of information technology it is the need of the day to digitalize and make the records permanent. This will help in both preservation and confidentiality.

REFERENCES

1. Sharma R K. Legal aspects of Medical record. In: How to face Medical Negligence in clinical practice Institute of medico legal publications, 1st edn. New Delhi: Institute of Medicolegal publications, 2019.p. 71–74.
2. Thomas J. Medical records and issues in negligence. *Indian J Urol* 2009; 25:384–88.
3. Asha Abhi *vs* Kanpur Medical Centre Pvt Ltd & Ors. (2014)NCDRC 3914.
4. Anoop Awasthi *vs* Dr.T.Kataria and others (2002) NCDRC 84 2002.
5. Vikash Arya S/o Shri Stayendra Kumar Arya *vs* Santokba Durlabhji Memorial Hospital and Medical Research Institute (2013) CDRC 34.

Section

7

Administrative Problems

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Chapter
33

Telephonic Consultation

RK Maheshwari

INTRODUCTION

Telephonic consultation is as old as the invention of telephone itself. Alexander Graham Bell's first recorded telephone call was for medical help after he spilt sulphuric acid on himself.[1] However, despite the widespread use of telephones in daily life and the range of possible benefits that telephonic consultation offers, their role in medical practice remains, for many clinicians, highly controversial because of medicolegal risks.

The different sections of the society (public, patients, health care providers including doctors, advocates and the legal system) have different notions/views on this aspect as every section analyses it by their own perspective. Needless to say it too has both pros and cons.

Advantage to Public

From the public/patient's perspective, telephonic consultations are very useful and highly cost effective. In the modern cash rich—time less society, it saves a lot of time. It can facilitate early diagnosis of cases. They are especially useful to patients residing in remote areas who cannot personally attend the clinician frequently and in emergency situations like COVID-19 pandemics when they are not allowed to move.[2,3]

Advantages to Health Care Providers

Telephonic consultation or other form of tele-consultations are beneficial to the healthcare providers as well. It helps to screen the cases thereby reducing the burden on secondary hospitals and also protects health personnels, viz. doctors (RMPs) and their staff from contracting infections from the patient.

Terminology

In the guidelines of Board of Governors (BoG) of MCI issued on 25 March 2020, many terminologies have been defined so as to dispense confusion. These guidelines are made to bridge gaps in legislation and the uncertainty of rules which pose a risk for both the doctors and their patients.

a. **RMP:** Registered Medical Practitioner is defined as a person who is enrolled in the State Medical Register or the Indian Medical Register under the IMC Act, 1956.[4]
b. **Health workers:** Health workers could be a (i) nurse, (ii) allied health professional, (iii) mid-level health practitioner, (iv) ANM or any other health worker designated by an appropriate authority.[4]

c. **First consult:** First consult means:
   i. The patient is consulting with the RMP for the first time; or
   ii. The patient has taken consultation with the RMP earlier, but >6 months have lapsed since the previous consultation; or
   iii. The patient has consulted with the RMP earlier, but for a different health condition.

d. **Follow-up consults:** The patient is consulting with the same doctor (RMP) within a period of six months of his/her previous in-person or physical consultation and this is for continuation of care of the same health condition.

   However, it *will not be considered* a follow-up if:
   i. Patient reports certain symptoms which are not related to same disease or condition and/or
   ii. RMP does not recall the context of previous treatment and given advice.

Consent

Telemedicine practice **must** never be done without consent of the patient. Consent is implied if the patient himself/herself calls the RMP for advise but if the health personnel (RMP, caregiver or health worker) makes the call than they must obtain consent of the patient before giving their expert advise. The consent, however, can be written or be given through electronic media (email, text or audio/video message) or even during the talk he can say—Yes, I consent to avail online consultation (nonphysical consultation through electronic media). The health professional must record the consent.[4]

Teleconsultation may be between: a. RMP and patient, b. Caregiver and RMP, c. RMP and RMP/specialist, d. Health worker and RMP, e. Emergency situations (RMP with patient or anonymous persons). Circumstances and implications in all these cases may not be same.[2–4]

a. **RMP and patient:** While giving advice to a patient on telephone the RMP has to rely on the patient's story, his own intuitions and experience but he has to keep in mind that none of these find any place in evidence-based medical practice.

   Telephonic advice by a RMP to the patient has both advantages as well as disadvantages.

   Advantages:
   a. That this may help the doctor in screening the patients thereby giving more time to serious patients rather than routine patients.
   b. It also can reduce the workload and reduces the need for home visits.
   c. This may enable doctors to keep a watch on their patients from a distance.
   d. Doctors can guide their patients during emergency.
   e. Follow-up of patient can be better.
   f. Telephonic consultation many a times improves confidence of patient in the treating physician.

   Disadvantages:
   a. Missing of visual clues and the findings the doctors elicits through physical examination (e.g. lump abdomen) thus chances of missing the correct diagnosis increases.
   b. Advise given by RMP may be misinterpreted by patient (especially if he is illiterate) or sometimes due to language problems.

c. There is always a possibility that a hurried doctor may close a telephonic consult prematurely without proper and structured history taking and may treat the patient without a proper diagnosis.
d. In some cases a 'bias' may exist against some patients who are frequent callers affecting the quality of advise.
e. Patient identification is a big issue. Chances of imposters representing the patient are very much there.
f. Medicolegal aspect. If anything goes wrong the doctor cannot claim immunity that he gave the advise in good faith, etc. The treating doctors must understand that duty of care arises even in telephonic consultation and their legal liability is same as of face consultation.

b. **Caregiver and RMP:** The caregiver could be a family member or any other person authorized by the patient. During telephonic consultation patient may or may not be by the side of caregiver. If the patient is a minor or if he/she is incapacitated (e.g. dementia, physical disability, etc.) the caregiver is deemed to be authorized to consult on behalf of the patient even if patient is not by his side. Otherwise caregiver must submit a formal authorization document.

   The other aspects would be same as consultation between RMP and the patient.

c. **Between RMP and RMP/specialist:** In many circumstances a treating RMP may seek the opinion of another RMP specialist for his patient. Since these advises are given after the treating RMP fully explains the condition of the patient to the consulting RMP—hence these types of consultation may be given in the interest of the patient especially for critical care monitoring where it is not possible to transfer the patient.

   In such situations also, consent of the patient must be taken (so that confidentiality clause is not breached) and the treating doctor must keep a record. The RMP asking for another RMP's advice or second opinion remains responsible for treatment and other decisions and recommendations given to the patient. However, the RMP giving the advise is accountable to the attending RMP for the quality of advice he or she provides, and should specify the conditions under which the advice is valid. He/she is obligated to decline participation if he or she lacks the knowledge, competence or sufficient patient information or data to provide a well-formed opinion.[5]

d. **Between health workers and RMP:** The health workers must also obtain the consent of the patient and should explain potential use and shortcomings (or limitations) of a telemedicine consultation. They should also confirm patient identity by asking patient's name, age, address, email id, phone number or any other identification that may be reasonable.[4]

   The treating RMP must try to know the identify of patient by asking his name, age, address or contact numbers or even email id to his/her satisfaction and they should also tell the patient about themselves. RMP should also confirm the patient's consent to prior to the consultation.

   The health worker must give a detailed explanation of the health problems to the RMP which can be supplemented by additional information by the patient, if necessary. If the RMP feels that he needs more information, he/she can ask for

additional information which may be shared in real time or shared later via email/text, as per the nature of such information, e.g. RMP may advice some laboratory and/or radiological tests for the patient. Consultation should be paused till the RMP gets the additional information or reports of lab tests, etc.[4] Health education may also be provided by the RMP as appropriate at any time.

e. **Emergency situations:** Many a times, e.g. during road side accidents, etc. even anonymous person may call a RMP. Telemedicine services in such situations should as far as possible be limited to first aid, life-saving measure, counseling and facilitating referral. In such situations, goal and objective should be to provide in-person care at the soonest. For example, in traumatic cases one should advise the opinion seeker about how to position neck to prevent further damage of spine in some cases. In all cases the patient must be advised for an in-person interaction with a RMP at the earliest.[4]

CHARGING FOR A TELEPHONIC CONSULT

Doctors can charge their patients for telephonic consult. Patient should be fully apprised about this. Instead of personally asking for a fee, which may offend some patients, it is better to give appointment/consultation through apps so that the patient pays before he confronts the doctor.

MCI GUIDELINES ON TELEMEDICINE[4]

Before Covid pandemic there was no law or guidelines as to how to practice telemedicine through electronic media (e.g. phone, video, emails, web-chat or apps). Lack of legislation vis-à-vis uncertainty of rules could put both doctor as well as patients in trouble. The Board of Governors (BoG) of MCI on 25 March 2020 under the IMC Act, 1956, has come out with guidelines on this issue.[4] The guideline document admits that this practice is not free from technological abuse. It has advantages, disadvantages as well as limitations, which can be mitigated through appropriate training, enforcement of standards, protocols and guidelines, which are to be used in conjunction with the other national clinical standards, protocols, policies and procedures.

The salient features of the guidelines are:

1. **Exclusions:** The guidelines specifically explicitly **exclude** the following:
   i. Specifications for hardware or software, infrastructure building and maintenance
   ii. Data management systems involved; standards and interoperability
   iii. Use of digital technology to conduct surgical or invasive procedures remotely
   iv. Other aspects of tele-health such as research and evaluation and continuing education of health care workers.
   v. Guidelines are applicable only for providing tele-consultation in India.
2. A RMP is entitled to provide telemedicine consultation to patients from any part of India.

   The tele-consultation providers (RMPs, etc.) are expected to uphold same ethical and professional norms and standards as are applicable to traditional in-person care albeit within the intrinsic limitations of telemedicine.[4]

3. The aim is to train all those RMPs who want to practice telemedicine with these guidelines as well as with the process and limitations of such e-practice:
   a. An online program will be developed and made available by the BoG in supersession of MCI. All teleconsultation providers will have to compulsorily complete the mandatory online course within a period of three years of its notification.
   b. Till the online program is notified or in the interim period, all teleconsultation providers need to follow these guidelines.
4. Both patient as well as the RMP should know each other's identity, so that the teleconsultation is not anonymous.
5. Patient's identity should be verified and confirmed by the RMP by asking his name, address, email id, contact no., registered id or any other appropriate way. Similarly, the RMP should see that there is a mechanism by which patient can verify the credentials and contact details of RMP.
6. An RMP should begin the consultation by telling the patient about his/her name and qualifications.
7. Multiple technologies (video, audio or text) can be used to deliver telemedicine consultations. Needless to say that all these have their positive and negative points and their appropriateness would depend on the fact that in which they are being used.
8. Consent of patient (implied or explicit) is a must.
9. All efforts must be made by the RMP to gather sufficient information about the patient's condition before coming to any professional judgment.
10. RMPs must keep a record of all such services.

Prescribing Medicines

Prescribing medicines after teleconsultation is at the professional discretion of concerned RMP. He/she should prescribe medicines only when he/she is fully satisfied that he/she has gathered adequate and relevant information about the patient's medical condition and in their opinion prescribed medicines will serve the best interest of the patient. Professional accountability of the RMP remains the same as in traditional physical or in-person consult. Moreover, drugs prescribed without an appropriate diagnosis/provisional diagnosis will amount to a professional misconduct.

Specific Restrictions

Depending upon the type and mode of consultation, certain limitations on prescribing drugs have been put.

The categories of medicines that can be prescribed are as under:

List O: It comprises those medicines which are safe to be prescribed through any mode of teleconsultation. In essence they would comprise medicines which are used for common conditions and are often available 'over the counter', e.g. paracetamol, ORS solutions, cough lozenges, antacids, etc. and medicines that may be deemed necessary during public health emergencies.

List A: This list includes drugs/formulations which may be prescribed at first teleconsultation or re-prescribing them during follow-up visits. This list includes

relatively safe medicines with a little potential for abuse. The list includes eye drops for conjunctivitis, anti-diabetic, anti-hypertensive drugs, bronchodilators, etc.

List B: In this list those drugs have been included which the treating RMP can prescribe to a patient who comes for follow-up consultation. The drugs of this list are in addition to those which have already been prescribed during first in person consult for same medical condition.

For example, a patient on atenolol can be prescribed ACE inhibitors like enalapril if blood pressure is not controlled.

Prohibited list: RMP providing consultation via telemedicine **cannot** prescribe medicines included in this list. These drugs, if used inappropriately, have a high potential of abuse and could harm the patient or the society, e.g. medicines listed in ***Schedule X*** of Drug and Cosmetic Act and Rules or any ***Narcotic Drugs*** and ***Psychotropic Substances*** listed in the Narcotic Drugs and Psychotropic Substances Act, 1985.

MEDICOLEGAL ASPECTS[2–7]

Till date there are no specific legislations for telemedicine hence if there is a case for medical negligence it has to be tried under the existing laws. In other words, there is no immunity in law if you are delivering the services through telemedicine. In the eye of law you are responsible for your advice whether given after face consult or whether given through technology (audio/video/chat).

The Hon'ble Supreme Court in the year 2009 (Martin F. D'Souza vs Mohd Ishfaq 3541/2002) laid down precautions which doctor/hospitals/nursing homes should take to protect themselves from complaints of medical negligence. In relation to telephonic consultation, the bench inferred that "No prescription should ordinarily be given without actual examination. The tendency to give prescription over the telephone, except in an acute emergency, should be avoided".

In the year 2018, the Bombay High Court (Deepa Sanjeev Pawaskar vs State of Maharashtra) turned down the anticipatory bail pleas of a doctor couple booked for the death of a woman patient under Section 304 of IPC (culpable homicide not amounting to murder). The court observed that the doctors, who were out of station, continued to prescribe drugs telephonically to the patient admitted in their hospital. The court observed that the medicines were administered on telephonic instructions without even enquiring about the symptoms or nature of the pain suffered by the patient. The court inferred that this is a case of culpable negligence amounting to gross negligence from the point of standard of care.

The IMA has also issued an advisory stating that—"A history of ailments and clinical examination is needed to prescribe any medication. Hence, telephonic consultation without seeing a patient is not ethically or legally valid."

In situations where a RMP advises to another RMP on phone, the aspect of professional negligence would remain the same for the local provider as well as the distant provider. The patient has to prove that there was a breach of care due to relationship between patient and the caregivers and this standard of care was not maintained by the caregivers leading to injury/suffering caused to the patient. However, shared responsibility will be an issue to face.

Hence, from medicolegal point of view, telephonic consultation must be avoided as far as possible and should be offered only to a known patient, and only after a prior face consult. Practically sometimes it becomes difficult (especially when patient is well known to you), hence one has to develop communication skill to say no in a very positive way and if at all advice is to be given it should be restricted to the symptomatic medicines after eliciting and ruling out the red flag symptoms being queried upon and concluding with the importance of physical examination.

If at all, telephonic consultations are to be given, the doctors must observe following precautions:[3]

- As soon as the phone connects, tell your name and ask caller's name and telephone number (so that he/she can be called back by another member of the team or if the call is disconnected). Confirm his identity and have his/her consent.
- Take a detailed and structured history.
- Explain him/her the hazards/shortfalls of telephonic advise.
- Check out that the patient can hear and understand you, and is in a suitable place to talk and is able to follow the instructions.
- The doctors should always keep in mind that the patient can also record the conversation as we are living in an era of smart phones. Hence, they must themselves always record the conversation since during evidence patient may present edited recordings.
- The patient must be asked to report to a nearby hospital as soon as possible for a face-to-face examination or should be told about when to come for follow-up.
- Before ending the conversation, the doctors must summarize the important points and ask the caller to repeat the advice given. This may be done several times during conversation so that he cannot claim that he did not understood the advice.
- Adverse effects of each drug that has been advised must be explained to the patients and they should be told how to deal when such effects appear.
- Confidentiality and privacy of conversation must be maintained. The data must not be shared without the consent of patient.
- Ask if he has any other questions and let him disconnect the call.
- Patients should be made aware for time at which they can call so that such calls be avoided during busy hours.
- Psychosocial problems must be avoided to be discussed on telephone.
- Avoid giving telephonic advise if the patient has never visited your clinic.
- If a patient asks for 'temporary' medication on telephone, advise him to consult the nearby doctor first.
- It will always be better if the patients who want to consult on telephone are asked to sign a document in which they admit that telephonic consultations are not as accurate as face consultations. They should also agree that concealing of some part of history could lead to misdiagnosis; also that drugs advised may have side-effects. They should also consent to recording of all conversation and data.

INSURANCE ISSUES

Many patients have medical insurance and since no prescription is generated in telephonic consultation the insurance companies may defer reimbursement of

consultation **fee**. Secondly, if the doctors have professional indemnity insurance, they must check whether their policy covers mishaps arising out of teleconsultation.

To conclude, teleconsultation is a dicey issue. The doctors/RMPs must weigh all pros and cons before giving advice. They must follow guidelines of MCI and should develop a good communication skill.

REFERENCES

1. Josip Car, Aziz Sheikh, Telephone consultations. *BMJ* 2003 May 3; 326(7396): 966–69.
2. Agarwal KK. Telephonic consultation. How safe are they ? Accessed at: file:///C:/Users dell2/Desktop/Telephonic%20consult/2%20Telephonic%20consultations_%20How%20safe%20are%20they_%20% E2%80%93%20From%20The%20Desk%20of%20 Dr%20K%20K%20 Aggarwal.html.
3. Gupta SG. Tips for telephone and electronic medical consultation. *Indian J Pediatr* 2013 Nov;80(11):944–8.
4. Telemedicine Practice Guidelines. Board of Governors, Medical Council of India, Delhi, 25 March 2020.
5. https://indiankanoon.org/doc/160266477.
6. https://www.thehindu.com/news/cities/Delhi/avoid-telephonic-consultation-requests-ima/article24710556.ece.
7. Verma Vivekanshu. Commercial telemedicine. *Journal of Indian Medicolegal and Ethics Association* April–June 2018, p 41–48.

Chapter
34

Law of Prescription Writing

Tushar Roy

INTRODUCTION

The commonest document that a doctor writes is a prescription. This prescription is a very important communication tool from the doctor to the patient. This communication is so important that even today prescriptions start with an appeal to God to guide the hand of the doctor, written in the form of the ancient symbol, Rx. The prescription is also the largest single type of legal document in the world. Recently, Smt Anupriya Patel, Minister of State for Health (Independent Charge) informed the Rajya Sabha in March 2018, that there are 10,41,395 allopathic doctors registered with the State Medical Councils or Medical Council of India as on 30th September, 2017.[1] Even if about 8.5 lakh doctors are actively practicing, each prescribing about 10 prescriptions a day, working for about 250 days a year—they would be generating more than 212 crore prescriptions a year in India alone. No other legal document in the world compares to this in sheer bulk.

OVERVIEW OF THE LAW

Even before we understand the law of prescribing it is important to understand a few basic tenets of the law. A most important maxim in law is "*Ignorentia juris non excusat*". It means that ignorance of the law is no excuse. When a law is enacted or a set to Rules promulgated and published in the Gazette of India, it is assumed that all citizens of India are now aware of the law or Rule. No one can now claim in any forum or court of law that one was not aware of such a law or Rule. As doctors we must therefore make ourselves aware of the relevant laws under which we practice.

The law that primarily governs our action as doctors is the *Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002*, promulgated by the Medical Council of India.[2] This must be followed by all doctors registered to practice modern scientific medicine or surgery (MSMS) defined as "modern scientific medicine in all its branches and includes surgery and obstetrics, but does not include veterinary medicine and surgery" in *Section 2 (g) of the Indian Medical Council Act, 1956*.[3] This is often (perhaps erroneously) called Allopathy.

There are many such laws that regulate the conduct of doctors. Some of them are given in Table 34.1.

Table 34.1: Some Acts and Rules governing prescription writing by doctors

1. Indian Evidence Act, 1872
2. Indian Medical Degrees Act, 1916
3. Drugs and Cosmetics Act, 1940
4. Drugs and Cosmetics Rules, 1945
5. Pharmacy Act, 1948
6. Drugs and Magic Remedies (Objectionable Advertisement) Act, 1954
7. Medical Termination of Pregnancy Act, 1971
8. Narcotic Drugs and Psychotropic Substances Act, 1985
9. Mental Health Act, 1987
10. Environmental Protection Act, 1986
11. Transplantation of Human Organ Act, 1994
12. Prenatal Sex Determination Test Act, 1994
13. Persons with Disabilities (Equal Opportunities and Full Participation) Act, 1995
14. Biomedical Waste (Management and Handling) Rules, 1998

WHAT IS A PRESCRIPTION?

After a detailed history taking, through physical examination and deep analysis of all available investigations, the doctor comes to a conclusion as to what ails the patient. He then formulates a strategy as to how to treat the patient. This treatment strategy involves a diet and exercise regimen along with necessary medication. He may also advise further investigations as he deems necessary. The legal document on which the doctor writes all this is the "Prescription".

This prescription is a legal document as described in *Section 29 of the Indian Penal Code, 1860*[4] and *Section 3 of the Indian Evidence Act, 1872*.[5] These Sections state that a document is "any matter expressed or described upon any substance—by means of letters, figures or marks or by more than one of those means and intended to be used or which may be used for the purpose of recording that matter".

Table 34.2: Some documents that the doctor is liable for

1. Prescription
2. IPD records
3. Discharge/death summaries
4. Patient reports—investigations
5. Medical certificates
6. Death certificates
7. Disability certificates
8. Fitness certificates

Doctors are responsible for many documents, some of which are enumerated in Table 34.2, the prescription being foremost amongst them.

At the outset, it must be clearly stated that generally all papers signed by the doctor are normally presumed to be a full prescription. So, if the document signed by the doctor is not a full prescription then that document should be properly labeled with labels such as requisition slip, investigations advised, discharge advice, discharge summary, medical certificate and so on.

It is now mandatory that all prescriptions be written in either the format for medical record laid down by the Medical Council of India, as given in Appendix 3 of the Ethics Regulations, or in the more recent format laid down in Annexure 2 of the Telemedicine Practice Guidelines, 2020,[6] promulgated by the Board of Governors in supersession of the Medical Council of India. Not following the format prescribed may amount to professional misconduct and invite disciplinary action from the State Medical

Council or Medical Council of India. This misconduct is defined in *Rule 7 of the Ethics Regulations*.

WHO CAN PRESCRIBE?

Only a Registered Medical Practitioner (RMP), a dentist or a veterinarian can write a prescription. Regarding MSMS (Allopathy) the following is noted in *Rule 1.1.3 of the Ethics Regulations*.

Rule 1.1.3: No person other than a doctor having qualification recognized by Medical Council of India and registered with Medical Council of India/State Medical Council (s) is allowed to practice the *Modern System of Medicine or Surgery*. A person obtaining qualification in any other system of medicine is not allowed to practice modern system of medicine in any form.

The Indian Medical Council Act, 1956 (IMCA, 1956) further defines recognized medical qualification in its S*ection 2 (h)*. It also defines the Indian and State Medical Register in *Section 2 (d) and Section 2 (k)* respectively.

It is therefore quite clear from the above, that only those doctors who have a recognized qualification and who are also registered with a Medical Council can write a prescription. Further, the prescription must only be limited to MSMS and one must not venture into other systems of medicine. Prescribing from any other system of medicine would mean that one is indulging in crosspathy and this may not only invite disciplinary action from the State Medical Council or Medical Council of India, but also redressal from the Consumer Forums and even compensation from the courts. One must also limit oneself not only to MSMS but also to one's narrow field of practice and must not step into a different or specialist field. Practice in a specialized field would require the doctor to have special qualification in that field. This is clearly stated in *Rule 7.20* of the Ethics Regulations.

Rule 7.20: "A physician shall not claim to be specialist unless he has a special qualification in that branch."

That there can be no crosspathy has been held by the Supreme Court of India in *Poonam Verma vs Ashwin Patel and others on 10 May, 1996*,[7] as well as in the *Delhi Medical Association vs Principal Secretary (Health), 2016*.[8] In addition, there can also be no cross-specialization practice as has been held in the recent case of *Goyal Hospital and Research Centre Pvt. Ltd., Jodhpur and others vs Kishan Shukla (R.P. No. 4023/2011)*,[9] where the National Consumer Disputes Redressal Commission (NCDRC), held that a doctor possessing an MD in Medicine cannot practice in the specialized field of cardiology.

The Drugs and Cosmetics Act, 1940 (DCA, 1940)[10] also defines "drug"in Section 3 *(b)* and "patent or proprietary medicine" in Section 3 *(h)*.

Section 3 *(b)* "drug" includes:

i. All medicines for internal or external use of human beings or animals and all substances intended to be used for or in the diagnosis, treatment, mitigation or prevention of any disease or disorder in human beings or animals, including preparations applied on human body for the purpose of repelling insects like mosquitoes.
ii. Such substances (other than food) intended to affect the structure or any function of the human body or intended to be used for the destruction of vermin or insects

which cause disease in human beings or animals, as may be specified from time to time by the central government by notification in the official gazette.

iii. All substances intended for use as components of a drug including empty gelatin capsules.

iv. Such devices intended for internal or external use in the diagnosis, treatment, mitigation or prevention of disease or disorder in human beings or animals, as may be specified from time to time by the central government by notification in the official gazette, after consultation with the Board.

Section 3 *(h) of DCA*, 1940 states that "patent or proprietary medicine" means, (ii) in relation to any other systems of medicine, a drug which is a remedy or prescription presented in a form ready for internal or external administration of human beings or animals and which is included in the edition of the Indian Pharmacopoeia for the time being or any other pharmacopoeia authorized in this behalf by the central government after consultation with the Drugs Technical Advisory Board constituted under Section 5.

PRESCRIPTION FORMAT

The minimum paper size of any prescription should be A5. It can be written in any language, but preferably in a language that the patient and the chemist can understand. The mandatory requirements as per the Ethics Regulations (including its Appendix 3) are the following:

1. Name of the doctor (as registered)
2. Qualifications and honors of the doctor
3. Designation of the doctor
4. State/Indian Medical Council Registration No.
5. Contact details of the doctor/hospital
6. Date of prescription
7. Name of patient
8. Age and sex of patient and weight if <12 years
9. Address (or phone) number of patient
10. Prescription should be legible or written in capital letters
11. The generic name of the medicine must be written (along with the brand name if the doctor so wishes).
12. Mention must be made of the dosage of the medicine, when and how often to take in a day, relationship to meal, how to take it and how long to take it.
13. No abbreviations should be used—must write micrograms instead of mcg (Table 34.3).
14. No Latin must be used—write thrice daily after meals instead of tds.
15. Note should be present if brand substitution is not allowed by the doctor.
16. Note should be present if refilling the prescription is allowed.
17. Note must be present if the doctor has dispensed the medicines.
18. The follow-up date should be clearly mentioned.
19. Must contain the signature of the doctor (with the doctor's name written below in case of government facility).

Table 34.3: Avoidable errors in prescription writing

1. Prefix zero before decimals – Write 0.5 instead of .5 to avoid misinterpretation of .5 as 5 – Digoxin 0.125 mg – Thyroxine 50 µg or 0.05 mg – Clonazepam 0.25 mg
2. Avoid unnecessary decimal points – Write 5 ml instead of 5.0 ml to avoid possible misinterpretation of 5.0 as 50
3. Avoid trailing zeros in decimals – Write 0.5 instead of .50 or 0.50 to avoid misinterpretation of .50 as 50
4. Write "ml" is used instead of "cc" or "cm^3" even though they are technically equivalent to avoid misinterpretation of 'c' as '0'
5. Write micrograms or µg
6. Abbreviation of the word units to IU can lead to a 10-fold overdose – 6 IU can be misinterpreted as 61 units instead of 6 units, resulting in death (Safer Prescribing Workbook, *Pharm J* 2001;267:193 (18))
7. Avoiding units such as 'teaspoons' or 'tablespoons'
8. Quantities of 1 g or more should be written (1 g, 1.5 g, etc.)
9. Write the quantities, frequency and duration clearly in full without abbreviations
10. Write intake of medicines in relationship to meals
11. Where the directions are 'as needed' is written – Specify indication and maximum quantity – For example, one tablet as required for anxiety, maximum of twice a day
12. Where possible specify events or times – Write after breakfast and dinner or at 8 am and 9 pm, instead of twice daily
13. Do not use older units and symbols of measure, like pints, ounces, grains (gr) or minims.

The following should preferably be written in the prescription:

1. Where the directions are "as needed"—please specify the indication and maximum quantity, e.g. as needed for anxiety, maximum of twice a day.
2. Where possible specify events or times should be written (after breakfast and dinner or at 8 am and 9 pm) instead of twice daily.
3. Warning about reactions and emergency with contact number (of doctor or hospital) must be written.
4. Special instructions on taking certain medication must be clearly mentioned
   - Alendronate—once a week early in the morning on an empty stomach with a full glass of water—swallow the tablet whole without any chewing or crushing—do not take any food or drink for the next 1 hour—do not lie down for the next 1 hour.
   - Dapagliflozin—please take about 2 L of fluid a day—taking it evenly throughout the day. Please keep your private parts clean.
   - Warfarin—please get the INR test done every month and let the doctor know if the INR is below 2.0 or above 3.0. Please follow the dietary precautions advised (list given). Please avoid intramuscular injections and "pain killers".

The relevant Rules of the Ethics Regulation pertaining to prescription writing are given below:

Rule 1.4.1: Every physician shall display the registration number accorded to him by the State Medical Council/Medical Council of India in his clinic and in all his prescriptions, certificates, money receipts given to his patients.

Rule 1.4.2: Physicians shall display as suffix to their names only recognized medical degrees or such certificates/diplomas and memberships/honours which confer professional knowledge or recognizes any exemplary qualification/achievements.

Rule 1.5: *Use of generic names of drugs:* Every physician should, as far as possible, prescribe drugs with generic names and he/she shall ensure that there is a rational prescription and use of drugs.

Rule 3.7.1: A physician shall clearly display his fees and other charges on the board of his chamber and/or the hospitals he is visiting. Prescription should also make clear if the physician himself dispensed any medicine.

Rule 3.7.2: A physician shall write his name and designation in full along with registration particulars in his prescription letter head.

Note: In government hospital where the patient load is heavy, the name of the prescribing doctor must be written below his/her signature.

Prescription should preferably be a computer printout, so that there is no difficulty in reading its contents. If this is not possible, then it should be handwritten in clear letters, preferably in capitals. Many a times bad handwriting has got doctors into trouble. Doctors were warned by the *Lucknow High Court in 2017*[11] as well as the *Allahabad High Court in 2018*[12] for illegible handwriting. A recent case of *Mrs Vimla vs Dr Ashwani Gupta and Sir Ganga Ram Hospital*[13] has been returned for adjudication to the Delhi Consumer Disputes Redressal Commission. In this case, Mrs Vimla has claimed a compensation of Rs 50 lakh, stating that the doctor's illegible handwriting caused the pharmacist to dispense the wrong medicine resulting in the death of her husband.

What should not be done?

There are certain things that should not be done.

1. One should not write one's name in very big letters or affix one's photo to his prescription.
2. One should not write any medical qualification or honors that are not recognized by the State or Medical Council of India.
3. One should not advertise—this includes Justdial, Practo, etc.
4. One may dispense medicines to one's own patients but must not run an "Open Shop".
5. One must not dispense any secret remedy—the generic name of the medicine must be clearly mentioned.
6. Never write "Not valid for medicolegal purposes: As all prescriptions and other documents are always valid for medicolegal purposes even if this statement is written.

A few other details are given below:

***Rule 6.1.2*:** Printing of self photograph, or any such material of publicity in the letter head or on sign board of the consulting room or any such clinical establishment shall be regarded as acts of self advertisement and unethical conduct on the part of the physician. However, printing of sketches, diagrams, picture of human system shall not be treated as unethical.

***Rule 6.3*:** Running an open shop (dispensing of drugs and appliances by physicians): A physician should not run an open shop for sale of medicine for dispensing

prescriptions prescribed by doctors other than himself or for sale of medical or surgical appliances. It is not unethical for a physician to prescribe or supply drugs, remedies or appliances as long as there is no exploitation of the patient. Drugs prescribed by a physician or brought from the market for a patient should explicitly state the proprietary formulae as well as generic name of the drug.

Rule 6.5: Secret remedies: The prescribing or dispensing by a physician of secret remedial agents of which he does not know the composition, or the manufacture or promotion of their use is unethical and as such prohibited. All the drugs prescribed by a physician should always carry a proprietary formula and clear name.

Rule 7.8: A registered medical practitioner shall not contravene the provisions of the Drugs and Cosmetics Act and Regulations made thereunder. Accordingly:

a. Prescribing steroids/psychotropic drugs when there is no absolute medical indication.
b. Selling Schedule 'H' and 'L' drugs and poisons to the public except to his patient; in contravention of the above provisions shall constitute gross professional misconduct on the part of the physician.

Rule 7.13: It is improper for a physician to use an unusually large sign board and write on it anything other than his name, qualifications obtained from a university or a statutory body, titles and name of his specialty, registration number including the name of the State Medical Council under which registered. The same should be the contents of his prescription papers. It is improper to affix a sign-board on a chemist's shop or in places where he does not reside or work.

There are also some special requirements for certain drugs mentions in certain schedules in the ***Drugs and Cosmetics Rules, 1945 (DCR, 1945)***.[14]

A "*Schedule X*" drugs can only be prescribed by a certain category of doctors. The prescription has to be given in duplicate and needs not only the signature of the doctor but also his personal and clinic stamp as the pharmacist has to maintain a register of such prescriptions and also has to retain a copy of the doctor's prescription. A new prescription is needed every time the medicines have to be repeated.

It is imperative that for the safety of the doctor, the following need to be done, even though there may or may not be a clear law in this regard:

1. All the drugs prescribed by a physician should always have a proprietary formula and clear name.
2. Keep copies of all prescription—as if any case is under dispute, the patient may not produce all the prescriptions and as per the *Indian Evidence Act, 1872 (5)*, it is the doctor who has to produce the prescription that he says he has given to the patient.
3. Prescription to be written in continuity on a A4 letterhead or have a prescription booklet so that continuity of the prescription is maintained—if possible number the prescriptions in series.
4. Do label all non-prescription papers appropriately, e.g. requisition slip, investigations slip, etc.
5. Avoid distractions while writing the prescription.
6. Avoid alterations/overwriting in the prescription. If this is unavoidable alterations should be clear and unambiguous and the doctor must add his initials near the altered item.

7. Never loan your prescription pads to anyone.
8. Write clearly or in Capital letters as illegibility is one of the major causes of medication error. In the United States of America, illegible handwriting has been responsible for the deaths of thousands annually, according to a report from the National Academies of Science's Institute of Medicine (IOM)[15] and has also been reported as the third leading cause of death in the United States of America.[16]

PRESCRIPTION WRITING AS PER THE TELEMEDICINE PRACTICE GUIDELINES, 2020

On 25th of March, 2020, The Board of Governors appointed in supersession of the Medical Council of India (in partnership with NITI Aayog) promulgated the Telemedicine Practice Guidelines (Telemedicine Guidelines). This will now constitute Appendix 5 of the Ethics Regulations.

As per these guidelines a specific format for the prescription has been laid down (Annexure 2). All requirements for prescription writing in the Ethics Regulations need to be followed. In addition, if the telemedicine consultation has not been initiated by the patient or is being taken on the patient's behalf by the caregiver or health worker or another RMP, then explicit consent must be taken and duly noted in the prescription. The same applies if the prescription is being transmitted to a pharmacy.

For purposes of prescription writing after teleconsultation, the mode of tele-consultation has been categorized as video or otherwise and the consultation itself has been categorized as *first consultation* or *follow-up consultation*. This categorization defines which medicines can or cannot be prescribed via teleconsultation.

3.6.1: *First consult means:* The patient is consulting with the RMP for the first time; or the patient has consulted with the RMP earlier, but more than 6 months have lapsed since the previous consultation; or the patient has consulted with the RMP earlier, but for a different health condition.

3.6.2: *Follow-up consult(s) means*: The patient is consulting with the same RMP within 6 months of his/her previous in-person consultation and this is for continuation of care of the same health condition. However, it will not be considered a follow up if: there are new symptoms that are not in the spectrum of the same health condition; and/or RMP does not recall the context of previous treatment and advice

Medicines for telemedicine purposes have been divided into four lists named O, A, B and prohibited.

List O: It will comprise those medicines which are safe to be prescribed through any mode of teleconsultation. In essence they would comprise medicines which are used for common conditions and are often available 'over-the-counter'. For instance, these medicines would include, paracetamol, ORS solutions, cough lozenges, etc.

Medicines that may be deemed necessary during public health emergencies.

List A: These medications are those which can be prescribed during the first consult which is a video consultation and are being re-prescribed for refill, in case of follow-up.

This would be an inclusion list, containing relatively safe medicines with low potential for abuse. It is a list of medication which RMP can prescribe in a patient who is undergoing follow-up consult, as a refill.

List B: It is a list of medication which RMP can prescribe in a patient who is undergoing follow-up consultation in addition to those which have been prescribed during in-person consult for the same medical condition.

Prohibited list: An RMP providing consultation via telemedicine cannot prescribe medicines in this list. These medicines have a high potential of abuse and could harm the patient or the society at large if used improperly.

Medicines listed in Schedule X of Drugs and Cosmetics Act and Rules or any Narcotic Drugs and Psychotropic Substances listed in the Narcotic Drugs and Psychotropic Substances Act, 1985.[17]

The drugs in the above mentioned list is summarized in Annexure 1 of the telemedicine guidelines (Annexure 3).

3.6.4.2: *Issue a prescription and transmit*: If the RMP has prescribed medicines, RMP shall issue a prescription as per the Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations and shall not contravene the provisions of the Drugs and Cosmetics Act and Rules. A sample format is suggested in Annexure 2.

RMP shall provide photo, scan, digital copy of a signed prescription or e-prescription to the patient via email or any messaging platform. In case the RMP is transmitting the prescription directly to a pharmacy, he/ she must ensure explicit consent of the patient that entitles him/her to get the medicines dispensed from any pharmacy of his/her choice.

Whenever the doctor gives advice via video or audio, he must be aware that this may be recorded and so must be very careful in what he says and how he says it. Also writing disclaimers during written transmission is advisable. An example of a disclaimer is given below.

1. This advice is of a preliminary nature and given as a professional courtesy only, based on the information that you have supplied. This does not and cannot replace an opinion given after full clinical and physical evaluation of the patient.
2. This is not the final opinion and is given without any responsibility on my part. You may use this opinion at your own risk and responsibility.
3. Medicines have been prescribed using branded-generic name, with the generic name given in brackets. Writing the generic name has been advised by the Medical Council of India. The government and the medicine manufacturing and formulating company are responsible for the quality assurance of all medicines including generic medicines. Poor quality medicines may adversely affect the outcome of your disease(s). The doctor is not responsible for any such adverse outcome due to poor quality of the medicine. Please choose your medicines carefully.

CONCLUSION

The prescription is a very important communication from the doctor to the patient. It is the largest single type of legal document in the world. Prescription writing is governed by various Laws and Rules that a doctor must know and comply with, so as to best treat the patient without incurring any liability.

REFERENCES

1. Medical Dialogues. Registered Doctors in India: Health Minister [Internet]. 2018 [cited 2020 Apr 20]. Available from: https://medicaldialogues.in/10-4-lakh-registered-doctors-in-india-maximum-in-maharashtra-health-minister.

2. Code of Medical Ethics Regulations, 2002 | MCI India [Internet]. [cited 2020 Apr 19]. Available from: https://www.mciindia.org/CMS/rules-regulations/code-of-medical-ethics-regulations-2002.
3. The Indian Medical Council Act, 1956 [Internet]. [cited 2020 Apr 19]. Available from: https://indiankanoon.org/doc/118783942/.
4. The Indian Penal Code, 1860 [Internet]. [cited 2020 Apr 19]. Available from: https://indiankanoon.org/doc/1569253/.
5. The Indian Evidence Act, 1872 [Internet]. [cited 2020 Apr 19]. Available from: https://indiankanoon.org/doc/1953529/.
6. Telemedicine Practice Guidelines [Internet]. [cited 2020 Apr 19]. Available from: https://www.mohfw.gov.in/pdf/Telemedicine.pdf.
7. Poonam Verma vs Ashwin Patel and others on 10 May, 1996 [Internet]. [cited 2020 Apr 19]. Available from: https://indiankanoon.org/doc/611474/.
8. Delhi Medical Association vs Principal Secretary (health) and ... on 8 April, 2016 [Internet]. [cited 2020 Apr 19]. Available from: https://indiankanoon.org/doc/95645241/.
9. Goyal Hospital and Research ... vs Kishan Gopal Shukla and another on 7 May, 2013 [Internet]. [cited 2020 Apr 19]. Available from: https://indiankanoon.org/doc/77679872/.
10. The Drugs and Cosmetics Act, 1940 [Internet]. [cited 2020 Apr 19]. Available from: https://indiankanoon.org/doc/1891720/.
11. Dec 15 NT|, 2017, Ist 14:18. High Court "Miffed" with Doctor's Bad Handwriting [Internet]. The Times of India. [cited 2020 Apr 19]. Available from: https://timesofindia.indiatimes.com/city/lucknow/high-court-miffed-with-doctors-bad-handwriting/articleshow/62082121.cms.
12. Allahabad HC Pulls up Doctor for Illegible Handwriting [Internet]. [cited 2020 Apr 19]. Available from: https://www.livelaw.in/finding-doctors-diagnosis-in-disability-certificates-illegible-allahabad-hc-pulls-him-up-seeks-explanation-read-order/.
13. Mrs Vimla vs Dr Ashwani Gupta and Sir Ganga Ram Hospital [Internet]. [cited 2020 Apr 19]. Available from: http://cms.nic.in/ncdrcusersWeb/GetJudgement.do?method=GetJudgement&caseidin=8%2F0%2FCC%2F46%2F2018&dtofhearing=2018-02-07.
14. The Drugs and Cosmetics Rules, 1945 [Internet]. [cited 2020 Apr 19]. Available from: https://indiankanoon.org/doc/16293633/.
15. Institute of Medicine (US) Committee on Quality of Health Care in America. To Err is Human: Building a Safer Health System [Internet]. Kohn LT, Corrigan JM, Donaldson MS, editors. Washington (DC): National Academies Press (US); 2000 [cited 2020 Apr 20]. Available from: http://www.ncbi.nlm.nih.gov/books/NBK225182/.
16. Makary MA, Daniel M. Medical Error - the Third Leading Cause of Death in the US. *BMJ* [Internet]. 2016 May 3 [cited 2020 Apr 19];353. Available from: https://www.bmj.com/content/353/bmj.i2139.
17. The Narcotic Drugs and Psychotropic Substances Act, 1985 [Internet]. [cited 2020 Apr 20]. Available from: https://indiankanoon.org/doc/1727139/.

Appendix

Format for Medical Record

(see Regulation 3.1)

1. Name of the patient: .....
2. Age: .....
3. Sex: .....
4. Address: .....

   .....

   .....
5. Occupation: .....
6. Date of 1st visit: .....
7. Clinical note (summary) of the case: .....

   .....
8. Prov.: Diagnosis: .....

   .....
9. Investigations advised with reports: .....

   .....
10. Diagnosis after investigation: .....
11. Advice: .....

Follow-up

Date: .....

Observations: .....

Signature in full: .....

Name of treating physician: .....

Annexure 1
Medicine Lists

List O

- **Common over-the-counter medications such as:**
  - Antipyretics: Paracetamol
  - Cough supplements: Lozenges
  - Cough/Common-cold medications (such as combinations of acetylcysteins, ammonium chloride, guaifensen, ambroxol, bromhexene, dextromethorphan)
  - ORS packets
  - Syrup zinc
  - Supplements: Iron and folic acid tablets, vitamin D, calcium supplements
- **Medications notified by Government of India in case from time to time on an emergency basis**
  - Such as chloroquine for malaria control for a specific endemic region, when notified by government.

List A

- **First consult medications (diagnosis done on video mode of consultation) such as:**
  - Ointments/lotion for skin ailments: Ointments clotrimazole, mupirocin, calamine lotion, benzyl benzoate lotion, etc.
  - Local ophthalmological drops such as: Ciprofloxacillin for conjunctivitis, etc.
  - Local ear drops such as: Clotrimazole ear drops, drops for ear wax, etc.
  - Follow-up consult for above medications.
- **Follow-up medications for chronic illness for 'refill' (on any mode of consultation) such as medications for:**
  - Hypertension: Enalapril, atenolol, etc.
  - Diabetes: Metformin, glibenclamide, etc.
  - Asthma: Salmetrol inhaler, etc.

List B

- **On follow-up, medications prescribed as 'add-on' to ongoing chronic medications to optimize management such as** for hypertension, e.g. add-on of thiazide diuretic with atenolol
  - Diabetes: Addition of sitagliptin to metformin, etc.

Annexure 2

6.1 SAMPLE PRESCRIPTION FORMAT

Registered Medical Practitioner's Name
Qualification
Registration Number
Address
Contact Details (Email and Phone Number)

Date of Consultation

Name of Patient | Age | Gender

Address | Height | Weight | LMP

Chest Complaints	Diagnosis or Provisional Diagnosis
Relevant Points from History	
Examination/Lab Functions	1. Name of Medicine (in capital letters only with generic name) drug form, strength, frequency of administration and duration
Suggested Investigations	2. Name of Medicine (in capital letters only with generic name) drug form, strength, frequency of administration and duration
	3. Name of Medicine (in capital letters only with generic name) drug form, strength, frequency of administration and duration

Special Instruction

RMPs Signature and Stamp

Note: The prescription is generated on a telecommunication

Table of medicine list which can or cannot be used during various teleconsultations

Matrix of the permissible drug list based on the type and mode of consultation

List	*Mode of consultation [video/audio/ text)*	*Nature of consultation [first-consultation/ follow-up)*	*List of medicines*
0	Any	Any	List O[1]
A	Video	First consultation Follow-up for continuation of medications	List A[2]
B	Any	Follow-up	List B[3]
Prohibited	Not to be prescribed	Not to be prescribed	Schedule X of Drugs and Cosmetics Act and Rules or any Narcotic Drugs and Psychotropic Substances listed in the Narcotic Drugs and Psychotropic Substances Act, 1985

1. This list included commonly used 'over-the-counter' medications such as paracetamol, oral rehydration solution (ORS) packets, antacids, etc.
2. This list includes usually prescribed medications for which diagnosis is possible only by video consultation such as antifungal medications for tinea cruris, ciprofloxocillin eye drops for conjunctivitis, etc. and refill medications for chronic diseases such as diabetes, hypertension, asthma, etc.
3. This list includes 'add-on' medications which are used to optimize an existing condition. For instance, if the patient is already on atenolol for hypertension and the blood pressure is not controlled, an ACE inhibitor such as enalapril.
4. For instance, anti-cancer drugs; narcotics such as morphine, codeine, etc.

Chapter
35

Defending a Case in Criminal and Civil Court

Mahesh Baldwa

The best way to defend yourself is to preempt your prosecutor.

DEFENDING CRIMINAL COURT CASE

Any Act or omission which is prohibited by law and is punishable by law is a crime. The punishment for such crime is decided by following procedures of criminal trial. The criminal trials in India are well established statutory, administrative and judicial framework. The whole criminal law consists of three main acts:

1. Indian Penal Code, 1860[1]
2. Code of Criminal Procedure, 1973[2]
3. Indian Evidence Act, 1872[3]

DICTUM IN CRIMINAL CASES

1. Unless proved negligent the doctor is not negligent.
2. **Medical board opinion** is must for pursuing medical negligence case in criminal court by prosecution as per supreme court three-judge bench in Jacob Mathew vs State of Punjab (2005) 6 SCC 1[4] and same is also followed in Martin F. D'Souza vs Mohd. Ishfaq (2009) 3 SCC 1[5], V Kishan Rao vs Nikhil Super Speciality Hospital (2010) 5 SCC 513.[6]
3. Deny all allegations from beginning till end of the criminal trial as accused
4. Wait patiently till prosecution establishes the case of negligence
5. Attend each and every date

Warrant cases where allegation is murdering a patient—very unusual for doctor to get such kind of criminal case: According to Section 2 (x) of Code of Criminal Procedure, 1973 a warrant case is one which relates to offenses punishable with death, imprisonment for life or imprisonment for a term exceeding two years. The trial in warrant cases starts either by the filing of FIR in a police station or by filing a complaint before a magistrate. Later, if the magistrate is satisfied that the offense is punishable for more than two years, he sends the case to the sessions court for trial. The process of sending it to sessions court is called "committing it to sessions court".

Important Features of a Warrant Case

- Charges must be mentioned in a warrant case
- Personal appearance of accused is mandatory

- A warrant case cannot be converted into a summons case
- The accused can examine and cross-examine the witnesses more than once.
- The magistrate should ensure that the provisions of Section 207 are applicable.
- Section 207 of CrPC 1973, include the supply of copies such as police report, FIR, statements recorded or any other relevant document to the accused.

The stages of trial in warrant cases are given from Section 238 to Section 250 of the Code of Criminal Procedure, 1973. Different Stages of Criminal Trial in a Warrant Case when instituted by the police report:

First information report: Under Section 154 of the Code of Criminal Procedure, a FIR or First Information Report is registered. FIR puts the case into motion. A FIR is information given by someone (aggrieved) to the police relating to the commitment of an offense.

Investigation: The next step after the filing of FIR is the investigation by the investigating officer. A conclusion is made by the investigating officer by examining facts and circumstances, collecting evidence, examining various persons and taking their statements in writing and all the other steps necessary for completing the investigation and then that conclusion is filed to the magistrate as a police report.

Charges: If after considering the police report and other important documents the accused is not discharged then the court frames charges under which he is to be trialled. In a warrant case, the charges should be framed in writing.

Plea of guilty: Section 241 of the Code of Criminal Procedure, 1973 talks about the plea of guilty, after framing of the charges the accused is given an opportunity to plead guilty, and the responsibility lies with the judge to ensure that the plea of guilty was voluntarily made. The judge may upon its discretion convict the accused.

Prosecution evidence: After the charges are framed, and the accused pleads guilty, then the court requires the prosecution to produce evidence to prove the guilt of the accused. The prosecution is required to support their evidence with statements from its witnesses. **This process is called "examination in chief".** The magistrate has the power to issue summons to any person as a witness or orders him to produce any document.

Statement of the accused: Section 313 of the Criminal Procedure Code gives an opportunity to the accused to be heard and explain the facts and circumstances of the case. The statements of accused are not recorded under oath and can be used against him in the trial.

Defence evidence: An opportunity is given to the accused in a case where he is not being acquitted to produce so as to defend his case. The defense can produce both oral and documentary evidence. In India, since the burden of proof is on the prosecution the defense, in general, is not required to give any defense evidence.

Judgement: The final decision of the court with reasons given in support of the acquittal or conviction of the accused is known as judgement. In case the accused is acquitted, the prosecution is given time to appeal against the order of the court. When the person is convicted, then both sides are invited to give arguments on the punishment which is to be awarded. This is usually done when the person is convicted of an offense whose punishment is life imprisonment or capital punishment.

Stages of criminal trial in a warrant case when private complaint institutes case—this is common against doctor under Section 304 (*a*) or 337 or 338 of Indian Penal Code.

Examination of complainant and its witnesses: On the filing of the complaint, the court will examine the complainant and its witnesses on the same day or any other day to decide whether any offence is made against the accused person or not.

Magistrate may order an inquiry: After examination of the complainant, the Magistrate may order an inquiry into the matter and submit a report for the same.

If sufficient evidence found: After examination of the complaint and the investigation report, the court may come to a conclusion whether the complaint is genuine or whether the prosecution has sufficient evidence against the accused or not.

If sufficient evidence not found: If the court does not find any sufficient material through which he can convict the accused, then the court will dismiss the complaint and record its reason for dismissal.

After examination of the complaint and the inquiry report, if the court thinks that the prosecution has a genuine case and there are sufficient material and evidence with the prosecution to charge the accused then the Magistrate may issue a warrant or a summon depending on the facts and circumstances. This is described as under

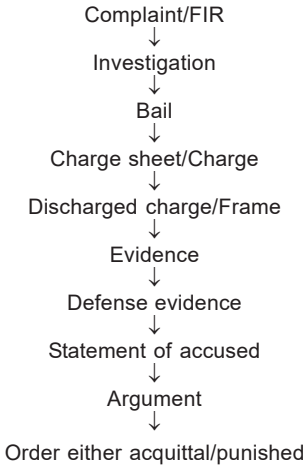

Fig. 35.1: Criminal case stages

Summon Cases

According to Section 2 (*w*) of Code of Criminal Procedure, 1973, Those cases in which an offense is punishable with an imprisonment of fewer than two years is a summon case. A summon case does not require the method of preparing the evidence. Nevertheless, a summon case can be converted into a warrant case by the magistrate if after looking into the case he thinks that the case is not a summon case.

Important Points about Summons Case

- A summons case can be converted into a warrant case.
- The person accused need not be present personally.

- The person accused should be informed about the charges orally. No need for framing the charges in writing.
- The accused gets only one opportunity to cross-examine the witnesses.
- The different stages of criminal trial in a summon case are given from Section 251 to Section 259 of the Code of Criminal Procedure.

Stages of Criminal Trial in a Summons Case

Pre-trial: In the pre-trial stage, the process such as filing of FIR and investigation is conducted.

Charges: In summons trials, charges are not framed in writing. The accused appears before the court or is brought before the court then the Magistrate would orally state the facts of the offense he is answerable.

Plea of guilty: The Magistrate after stating the facts of the offence will ask the accused if he pleads guilty or has any defense to support his case. If the accused pleads guilty, the Magistrate records the statement in the words of the accused as far as possible and may convict him on his discretion.

Plea of guilty and absence of the accused: In cases, where the accused wants to plead guilty without appearing in the court, the accused is supposed to send Rs 1000 by post or through a messenger (lawyer) to the Magistrate. The absentee should also send a letter containing an acceptance of guilt and the amount of fine provided in the summons. The Magistrate can on his discretion convict the accused.

Prosecution and defense evidence: In summons case, the procedure followed is very simple and elaborate procedures are eliminated. If the accused does not plead guilty, then the process of trial starts. The prosecution and the defense are asked to present evidence in support of their cases. The Magistrate is also empowered to take the statement of the accused.

Judgement: When the sentence is pronounced in a summons case, the parties need not argue on the amount of punishment given. The sentence is the sole discretion of the judge. If the accused is acquitted, the prosecution has the right to appeal. This right to appeal is also extended to the accused.

Summary Trial

Cases which generally take only one or two hearings to decide the matter comes under this category. The summary trials are reserved for small offences to reduce the burden on courts and to save time and money. Those cases in which an offence is punishable with an imprisonment of not more than six months can be tried in a summary way. The point worth noting is that, if the case is being tried in a summary way, a person cannot be awarded a punishment of imprisonment for more than three months.

The trial procedure is provided from Section 260 to Section 265 of the Code of Criminal Procedure.

Stages of Criminal Trial in Summary Cases

The procedure followed in the summary trial is similar to summons case.

Imprisonment up to three months can be passed.

In the judgement of a summary trial, the judge should record the substance of the evidence and a brief statement of the finding of the court with reasons.

Are procedures in consumer court and other civil courts like civil judge, special civil judge, and permanent lok adalat same except criminal court which is described above?

Yes, most of the procedures in civil courts follow civil procedure code in limited or unlimited form. Consumer courts are one of the special kinds of civil court. The main difference between civil courts and criminal courts is remedy sought by complainant. If complainant wants you to be jailed then he/she will seek criminal courts otherwise for monetary compensation shall seek civil or consumer courts.

OUTSIDE COURT SETTLEMENT PRIOR TO RECEIVING NOTICE

Q1. Should doctor yield to patient or his relatives demand of asking money for alleged negligence when you feel that you were not at all negligent?

Ans: No. This will just postpone a problem. Reason being such patients is more likely to take you through legal process once you pay them.

Q2. Should doctor yield to patient or his relatives demand of asking money for alleged negligence if you feel that you were negligent.

Ans: Depends upon facts and circumstance of attitude of relatives. If attitude is perceived to be favorable then get a "memorandum of out of court settlement for accord and satisfaction" be drafted and signed by following a proper procedure. Take lawyers or medicolegal advisor's help in drafting and executing the procedure. It is not recommended for bad attitude patient's relatives.

Receiving Legal Notice and Replying it

Q3. Should one receive a legal notice sent by lawyer?

Ans: Yes, as doctor has an opportunity to answer, can focus on planning future defense if case is filed in any court .

Q4. Should one reply legal notice himself or through lawyer?

Ans: Yes, doctor should reply legal notice through lawyer in consultation with medicolegal advisor's mind.

Q5. Why doctor should reply legal notice through lawyer in consultation with medicolegal advisor's mind?

Ans: Lawyer cannot differentiate and give the required flavor that doctor gave treatment diligently, prudently with due care and caution. Lawyer's reply is mechanical denying alleged negligence. Lawyers usually have no detail knowledge of medicine. Lawyers are not able to explain inherent and unavoidable medical complications. Medical complications are ubiquitous. Lawyers cannot understand intricate mechanisms involved in body medical physiology and underlying medical pathology. This lands lawyers to draw half backed conclusions in cases of alleged medical negligence. Most lawyers wish to depend upon procedural aspects of law restricting them to the law of limitation, law of alibi, law of evidence. Lawyers hardly touch upon medical facts to defend the case. Lawyers land their doctor clients in an odious situation of presenting the case alien to medical fraternity. Lawyer working in tandem with medicolegal advisor can bring forth medical facts in legal notice reply facts circumstances which led to death, disability, transfer or increased expenses or hardships to relatives more convincingly for which doctor was not responsible.

Outside Court Settlement after Receiving Notice by Negotiations

Q6. Should doctor yield legal notice demand of asking money for alleged negligence by negotiations with patient's lawyer or your own lawyer?

Ans: Chances of success are remote yet explore the possibility. But guiding principles are same as described above for "outside court settlement".

Post Notice: Sleep over the Matter or be Proactive

Q7. What is the usual advice of lawyer in post notice period?

Ans: Lawyers says that wait till the next legal move of the patient. Lawyers attitude is do not take till trouble actually troubles doctor then only take trouble in hurry to address the trouble leaves no time for doctor to gather the evidence which is vital to the alleged medical negligence case.

Q8. Should one be proactive in preparing defense?

Ans: Medicolegal advice is "Yes", because a forewarned doctor is forearmed in gathering evidence. In medical negligence case it is very time consuming to collect required evidence. Hurriedly collected scientific medical literature, evidence of affidavits of eye witness and expert witness are less useful if not corroborated with pleadings in written statement, affidavit of evidence and rejoinders.

Nature of Evidence

Q9. What is the nature of evidence courts require?

Ans: Courts require evidence for diligence, prudence, care and caution in the alleged medical negligence case. Case papers explaining the process of disease, treatment and surgery, complications and their timely treatment needs to be properly explained as part of documentary evidence.

Prudence

Q10. What is the evidence of prudence of doctor?

Ans: To prove doctors prudence in court evidence showing doctors qualifications, experience, competence and skills is required.

Qualifications

Q11. What is the evidence of qualifications?

Ans: To prove prudence based on doctors qualifications in court as evidence, only submit ethics and registration board of National Medical Council Act, 2019 recognized qualifications and say on the basis of that you have treated the case.

Q12. How to plead prudence when postgraduate qualification which is not recognized by Medical Council of India or State Medical Council?

Ans: To prove prudence when postgraduate qualification which is not recognized by Medical Council of India or State Medical Council you have to prepare your evidence of prudence based MBBS qualifications only. Avoid writing on your letterhead words expert or specialist or "Daksha" or "Tagya" or "Visheshgya" so as to avoid negligence per se observation of court. Instead such doctors should safely plead and write on their letterheads words like "advisor" or "counselor" or "Trained" or "Experienced" "Salahagar" or "Anubhavi". Never plead or claim that you are by virtue of qualification and expert or specialist or superspecialist in the field if your degree is

not MCI recognized. Claiming in court that your qualified postgraduate specialist/expert if your degree is not MCI recognized may put you in gross legal trouble. Practicing medicine in the field of that any specialty on the basis of experience and training is allowed but do not plead or claim to possess the unrecognized qualification in the court of law in medical negligence case.

When Experience is Considered Skill

Q13. What is the evidence of experience?

Ans: To prove prudence based on doctors experience in court as evidence, submit work experience certificates of medical colleges, medical institutes, and attendance of medical workshop certificates. Prepare a good bio-data with number of surgeries/procedures done.

Competence

Q14: What is the evidence of MBBS doctor's field of competence?

Ans: To prove prudence of field of competence of MBBS doctors in court as evidence, MBBS person should submit and I, II and III MBBS mark sheets from medical college showing study, knowledge, competence and skill in conducting the treatment given in alleged medical negligence. MBBS person should submit transcript from medical college. Also prepare a good bio-data with number of surgeries/procedures done. Submit attendance of medical workshop certificates. One has to say very clearly that on the basis of MBBS qualifications, one has treated the case and one is not claiming to have treated the case in the capacity of qualified specialist/expert in that specialty.

Q. 15. Can MBBS doctor plead that one is competent to do give care to any diseases belonging to medical specialty usually given by qualified specialist in field possessing postgraduate diploma or degree?

Ans: Yes, there is no legal bar in conducting the treatment if one is competent to conduct treatment in cases belonging to any medical specialty as long as one does not claim to be qualified specialist in that field of senility. MBBS should not claim through signboards, letterheads that he is qualified specialist in that medical field.

Prudence of Skill

Q16. How to plead prudence of skill?

Ans: The prudence of skill is combination of qualifications, work experience and competence, which should be reflected in bio-data of doctor and case paper showing conduct of treatment of case to be in a peer approved way. Collected scientific medical literature, evidence of affidavits of eye-witness and expert witness are less useful if not corroborated with pleadings in written statement, affidavit of evidence and rejoinders.

Receive or Refuse Notice

Q17. Should you receive or refuse notice from any courts?

Ans: Receive summons from any courts and never refuse summons. Not defending yourself/hospital/nursing home properly in a case of alleged negligence shall enable the court to pass ex-parte order of negligence and compensation against you. That will send wrong message to other doctors, press and media precedent that doctors are

generally negligent and not law abiding. This will cause spiraling of premiums of professional indemnity insurance by insurance companies and the medical professionals resorting to defensive practice.

Time Given for Filing Written Statement

Q18. In how many days one should prepare and file to answer complaints?

Ans: Usually within 45 days or date is specified in the summons.

Q19. What is the legal name for answer/reply to complaint?

Ans: Legal name for answer/reply of any complaint is written version or written statement (WS) of opposite party (OP) or respondent.

Study of Complaint

Q20. What is title of complaint and how to read title of complaint with a view to reply?

Ans: Title of complaint contains name of court, place, name of complainant and opposite parties and their addresses. While one reads complaint one will find that it starts with the name of court and place where it is situated. It should have the territorial jurisdiction over place where you practice. Under new Consumer Protection Act, 2019 (new CPA) the complainant can file anywhere, where he/she resides. Read the name of complainant whether he is patient himself, guardian, parent, any organization or legal heir. If it does not fall in that category then, challenge. Then read name of OP or all OPs and see whether you are sued in your own name or in the name of hospital/nursing home. You have to see whether it is beneficial to reply separately or jointly. If you have, individual medical indemnity policy replies separately. If you have additional hospital/establishment error and omission policy then reply jointly. See whether insurance party is named as OP or not? If not then make an application to add insurance company a party. Also see who else treated this patient and if possible and necessary make an application to add their names as OP.

Q21. How to read, typical initial six to eight of paragraphs of complaint with a view to reply?

Ans: Paragraph 1 of complaint usually describes the age, occupation and income or earning capabilities of the patient. Paragraph 2 of complaint usually describes what patient was suffering from and laymen diagnosis and in complainant's view what treatment was required to be given. Paragraph 3 of C, usually describes, doctors capabilities/incapabilities of leaving mob while doing surgery, infrastructure and promises made to patient. Paragraph 4 of complaint usually describes, what payment was made? Paragraph 5 of complaint usually describes whether doctor issued receipts and for some he did not issue receipts. Paragraph 6 of complaint usually makes a point blank blunt allegation of negligence in conducting treatment, diagnosis or investigations, anesthesia, operation or procedure. Paragraph 7 of complaint describes if patient is transferred to some other hospital then that event, those doctors' views and money spent here. Paragraph 8 of complaint is about the nurses/staff/assistants or any such related issue.

Q22. How to read typical middle six to eight of paragraphs of complaint with a view to reply?

Ans: Paragraphs 9 to 12 of complaint will describe in laymen details about doctors' capabilities/incapabilities, infrastructure, promises made to patient by repeating same

thing again and again irritatingly. Paragraphs 13 to 18 of complaint will describe in laymen details about alleged negligence in conducting treatment, diagnosis or investigations, anesthesia, operation or procedure by repeating same thing again and again. Paragraphs 19 to 22 of complaint will describe in laymen details about transferred to some other hospital then that event, those doctors' views and money spent there, by repeating same thing again and again.

Q23. How to read typical penultimate three to six of paragraphs of complaint with a view to reply complaint?

Ans: Paragraphs 22 to 25 of complaint will describe in laymen correlation between negligence and loss suffered in details by repeating same thing again and again. Paragraphs 25 to 27 of complaint will describe jurisdiction, cause of action and fees paid with petition under new Consumer Protection Act, 2019. Hopefully, new Consumer Protection Act, 2019 should exclude health care.

Q24: How to read typical prayer clause paragraphs of complaint with a view to reply complaint?

Ans: Summarize alleged negligence causing damages and financial hardships. If it is consumer courts they usually will ask compensation of Rs 50 lakh in district court or more than Rs 50 lakh to 2 crore in state commission. National commission demand is >2 crore.

Summary and Classification of Allegations

Q25. How to classify the allegations in complaint with a view to reply complaint?

Ans: Usually allegations are related to mean that doctor is not qualified, there was inadequate infrastructure, nurses and staff members are not qualified did not attend, doctor delayed in diagnosing or misdiagnosis or delay in investigating or treating the patient. Doctor was not present during emergency. Consent was not obtained. There was overcharging. Transfer to higher center delayed. Plethoras of derogatory words are used against medical profession, doctors, nurses and staff members. Sometimes allegations of unnecessary investigations and treatment are used. Excessive irrational compensation is asked in complaint.

Written Statements (WS) under New Consumer Protection Act, 2019 or any other Court

Q26. How to reply initial six to eight of paragraphs of complaint in written statement (WS) of doctor/opposite party (OP)?

Ans: Reply to paragraph 1 of complaint that patient did not inform/misinformed you about occupation and income or earning capabilities. Patient is not a consumer. Reply to paragraph 2 of complaint ignoring what patient has described what patient was suffering from and laymen, his diagnosis and in his about treatment and write what you have written in your case paper. Reply to paragraph 3 of complaint agreeing to your capabilities as per what degrees medical council registration shows and deny incapabilities in qualification, knowledge, experience, skill, infrastructure by attaching required certificates to prove the same. Deny any promises or guarantee made to patient, as professionals do not guarantee cure. Make a note of hiding previous illnesses. Reply to paragraph 4 of complaint; deny if payment made was less and describe actual payment made and ask complainant to produce receipts in court. Reply to paragraph 5 of complaint deny, not issuing receipts. Reply to paragraph 6 of complaint deny

point blank blunt all allegations of negligence in conducting treatment, diagnosis or investigations, anesthesia, operation or procedure and say it was conducted diligently, prudently with due care and caution. Reply to paragraph 7 of complaint that patient is transferred to some other hospital diligently, prudently with due care and caution and give reason for transfer. Deny if you do not agree with doctor's views or confirm it. Deny money spent there and say you are not responsible for same as you did everything diligently, prudently with due care and caution. Reply to paragraph 8 of complaint about the staff/assistants that they worked under your direct supervision and directions and they are individually for any action/inactions as you were deciding authority on conduct of all aspects related to patient.

Q27. How to reply to middle six to eight of paragraphs of complaint?

Ans: Reply by saying paragraphs 9 to 12 of complaint is repetition of allegations, doctors' capabilities/incapabilities, infrastructure, promises made to patient by repeating same thing again and again irritatingly and same is already replied in earlier paragraphs. Reply to paragraphs 13 to 18 of complaint by denying all allegations and saying it is laymen view and details about alleged negligence in conducting treatment, diagnosis or investigations, anesthesia, failed operation or procedure by repeating same thing again and again, which is replied earlier. Reply to paragraphs 19 to 22 of complaint deny allegations by saying it is laymen details about transfer and your conduct of transfer is described in earlier para. Deny all allegations based on other hospital doctors' views. Deny allegations about money spent there and say it is being unnecessarily repeated describing same wrong things again and again.

Q28. How to reply to penultimate three to six of paragraphs of complaint?

Ans: Reply to paragraphs 22 to 25 of complaint by saying that it is laymen correlation between negligence and loss suffered and enclose scientific literature and affidavit of expert from other doctors supporting your view. Reply to Paragraphs 25 to 27 of complaint and say whether jurisdiction, cause of action and fees paid with petition are correct or incorrect. In case, it is incorrect then one has to move separate miscellaneous application to lodge objection to jurisdiction, cause of action.

Q29. How to reply prayer clause paragraphs of complaint?

Ans: Deny alleged negligence causing damages and financial hardships point blank. Deny having incurred any liability of paying anything to complaint. All you say that alleged negligence is wrong and denied since you did everything diligently, prudently with due care and caution which is evident from certificates of qualification, experience, skill and competence, photographs show infrastructure, scientific literature shows complications which can occur leading to death or disability and same is also.

Synopsis or how to Summarize Written Statement (WS)

Q30. How to reply by classifying the allegations of complaint and replying in summary way?

Ans: Deny allegations are related to mean that doctor is not qualified, there was inadequate infrastructure by certificates of qualification, experience, skill and competence, photographs, deny staff members did not attend supported by affidavit of eye witness, deny that doctor conducted delayed in diagnosing or misdiagnosis or delay in investigating or treating the patient on the basis of case papers. Deny that doctor was not present during emergency supported by affidavit of eyewitnesses.

Deny consent was not obtained by showing consent. Deny overcharging by enclosing carbon copy of actual bill. Transfer to higher center delayed. Deny plethora of derogatory words that are used against medical profession, doctors, nurses and staff members by threatening to take legal action separately for these remarks. Deny allegations of unnecessary investigations and treatment by scientific literature and affidavit of expert witness. Prove that compensation asked is excessive and irrational of complaint and in any case you are not liable as you conducted everything diligently, prudently with due care and caution as described above.

Q31. What general precautions should one take to reply by classifying the allegations of complaint and replying in summary way?

Ans: First and foremost denying all allegations of negligence and deficiency in service needs to be emphasized. Whatever pleas in defense are raised they should be supported by evidence in the first instance of mentioning specifically in reply to the complaint. Subsequent new explanation/pleas during hearing of the case are liable to be rejected.

Legal Technical Defences[7]

Q32. What is legal technical defenses for doctors/hospitals in preparing WS defense?

Ans: Legal technical defenses for doctors/hospitals are:

a. Cause of action
b. Pecuniary/territorial jurisdiction
c. Non-joinder or mis-joinder of parties
d. Free service given
e. *No locus standi* as legal representative (LR)
f. *Case subjudice* civil/criminal court
g. The compensation claimed has been inflated or exaggerated for bench hunting of jurisdiction of the court/commission suitable to complainant.
h. The complaint is time-barred
i. The complaint is frivolous and vexatious and liable to be dismissed under Section 26 of the Act.
j. CC has complicated issues involved; requiring recording of evidence of experts, hence complaint case should be filed in a civil court.
k. Doctor is dead, i.e. action *personalis moritur-cum-persona*
l. In case, there is indemnity insurance or hospital error and omission policy make insurance company a party to suit.

Factual Defence[7]

Q33. What is factual defense for doctors/hospitals in preparing written statement (WS) defense?

Ans: Factual defenses are:

a. Case paper/discharge summary record of patient
b. Detailed bio-data of doctor supported by qualifications, experience, *training, experience, expertise,* certificates/appreciation certificates/awards/attendance at various updates, conferences, workshops
c. Photographs showing infrastructure
d. Affidavit of eyewitness.

Affidavits of Expert Doctors and Scientific Literature[7]

Q34. What is defense by supplying affidavits of expert doctors and scientific literature in preparing WS defense?

Ans: Annexure 5 to 10 affidavits of expert doctors to state that you conducted everything diligently, prudently with due care and caution. Also annexure 5 to 10 scientific literature to show you conducted everything diligently, prudently with due care and caution as per standard textbook way. If available, in case of death, if medical board was set up by police then its favorable report or favorable postmortem report or favorable civil surgeon report is valuable. In case of death due to poisoning, favorable forensic laboratory report is valuable. In case of alleged disability, submit any favorable disability certificate or report. In case of transfer next hospital case records, discharge card to be submitted if favorable.

Other Residual Defences[7]

Q35. What are other residual defenses to be written in WS defense?

Ans: They are:

a. Complainant not coming to the court with clean hands, i.e. he has suppressed material facts, e.g. previous illness, treatment, etc.
b. There are inconsistencies between notices sent directly or through a lawyer/consumer groups and the complaint made in the court. The inconsistencies should be specifically pointed out.
c. Circumstances of the case, viz. there was, emergency, lack of facilities (e.g. rural area), no one to give history of patient's illness, etc.
d. Burden of proof of duty of care, breach of that duty; causation, damage, etc. is on the complainant.
e. Claim against doctor/hospital usually fails if it can be proved that there was a break in the chain of causation *(novus actus interveniens).* This is where an Act by a third party supersedes the original negligent Act of the OP/doctor/defendant. The court must decide whether the original Act of the defendant was responsible for the damage or if the intervening Act constitutes a *novus actus interveniens,* that is, the second Act caused the damage. The second Act could be an intervening Act by a third party or an intervening Act by the claimant himself.
f. Consultation/treatment taken by patient from other doctors/other systems of medicine simultaneously. This will subdue/dilute the alleged negligence of OP as many other reasons for occurrence of damage make it impossible to pinpoint at OP.
g. *Contributory negligence*: *As* in all other defenses, this defense must be pleaded in the first instance showing how exactly it contributed to damage caused by alleged medical negligence.

Basics of Rules of Drafting of Reply[7]

Q36. What are other usual basics of rules of drafting of reply/defense by or on behalf of the doctor/hospital?

Ans: The very purpose of defense drafting is to create a record, which makes part and parcel of proceedings in court and helpful even when case is lost and one needs to

appeal. Since you cannot add/alter/amend or take a new plea in appeal court. Defense should be in writing which should contain plea about the doctor's/hospital's denial/clarification/explaining cause and effect relationship in reply to the complaint.

It is necessary to reply the complaint para-wise and the allegations needs denial or explanation and your comments should be written down para-wise against each of the allegations narrated in complaint.

Defense (reply) is legal opportunity to narrate or state in written format to reply each of the allegations made by the complainant as well as provides one's own version of the matters under dispute. A basic legal and fundamental purpose of the defense is that, when read in tandem or conjunction with the complaint, it should make clear those disputed points on which parties are not in agreeing to.

The most important rule in drafting a defense is to ensure that *every* material allegation in the complaint is properly answered and dealt with supporting evidence as annexure.

Dealing with an Allegation Against the Doctor/Hospital[7]

Q37. What are dealing with an allegation against the doctor/hospital?

Ans: You have to *admit and reply on statement in your favor. You have to deny* all unfavorable statements and allegations with explanation with evidence to show defendant's side of the story is wrong, false, vexatious, motivated to extract money.

Sometimes the defendant has no evidence to rebut the allegation with the help of medical record then look whether it can be supported by affidavit of eyewitness or affidavit of expert witness. Court takes it for granted that if any allegation, which is neither denied nor admitted in your answer, is, deemed to have been admitted as evidence without proof. The best way to make sure that nothing is admitted by above said legal dictum of court presumption of guilt since allegation is neither denied nor admitted; is by dealing with each of the complainant's allegations one by one in para-wise manner. The defendant's response to the allegations made by the complainant gives proper picture of whole event on larger canvass with respect to case. Court is prompted to works with broad framework of the defense with respect to complaint. It gives court not only fair idea about disputes between the parties. Whenever a single paragraph contains more than one allegation, each must be specifically admitted or denied. When the allegation is denied, there is need to give elaborate explanation with evidence in that paragraph.

In some cases, a paragraph may appear to consist of one allegation while in fact containing a central allegation and one or more subordinate allegations. Therefore, it is essential that while dealing with a paragraph of the complainant, subordinate allegations should not be given a pass or overlooked. Simply admitting allegations in the paragraph would therefore admit subordinate allegations that the defendant should deny or traverse it diligently.

The defendant should not deny and traverse any *indirect or implied allegations* in the complainant's paragraphs with specific reply with evidence.

But where a single paragraph of the complaint contains multiple and complicated allegations, the appropriate reply/answer or response may be a conclusion of admissions, non-admissions and/or denials or to traverse the paragraph by a combination of non-admissions and denials with proper evidence. It should also be

particularly noted that in drafting the reply, the proper approach is to deny or traverse both the fact and statement or narrations causing damage and its extent since they are not supported by disability certificate or expert witness by complainant.

Pleading Additional Facts by Doctor/Hospital[7]

Q38. What are pleading additional facts by doctor/hospital?

Ans: An important function of the defense is to plead additional facts, which fill gaps and explain and clarify or correct cause and effect relationship based on theory of percentage of complications or death occurring while treating the illness. All errors in the complainant's account of the events alleged to have given rise to a cause of action should be accepted/denied or explained. It should be in conformity with reply to notice received, all the allegations made therein should be rebutted in as short a language as possible reserving therein the right to take further appropriate defense after the filing of complaint.

Procedural Defenses/Action Taken by Doctor/Hospital[7]

Q39. What are the procedural defenses/action to be taken by doctor/hospital?

Ans: As mentioned above once again take objection to the pecuniary, territorial jurisdiction of the any court as also that the complaint raises complicated questions of fact and law and/or requires leading of voluminous evidence should be raised if applicable.

Sworn Verifications Required

Q40. How a written statement (WS) should be properly verified and sworn.

Ans: Written statement (WS) should be properly verified and sworn in front of notary or registrar of court concerned

Q41. How all affidavits of eye or expert witness are properly verified and sworn?

Ans: The affidavits of eye or expert witness should be properly verified and sworn in front of notary or registrar of court concerned. Expert witness on letterhead has less value and liable for cross-examination more often than sworn affidavit.

File Objection for the Complaint without Affidavit[7]

Q42. How to file objection for the complaint without affidavit and which has not been properly verified, sworn or attested.

Ans: Move a miscellaneous application to file objection for the complaint without affidavit and which has not been properly verified, sworn or attested by notary and prayer clause should ask for dismissal with cost.

Application for Cross-examination of the Witnesses[7]

Q43. How to file application for cross-examination the witnesses, and re-butt the evidence of the complainant?

Ans: Move a separate miscellaneous application for cross-examination the witnesses of the complaint and prayer clause should ask for dismissal with cost if they do not arrange for cross examination.

Q44. How to file application, objections for additional pleas to be raised after receipt of complaint in rejoinder?

Ans: Doctor has to file application objections for additional pleas to be raised after receipt of complaint in rejoinder by complainant. Move a separate miscellaneous application for objecting to additional pleas to be raised after receipt of complainant's cross-objection in rejoinder then prayer clause should ask for dismissal with cost if they do not arrange for cross examination.

Affidavit of Evidence[7]

Q45. How to file affidavit of evidence?

Ans: Submit affidavit of expert witness and file a list of expert witnesses with affidavit of evidence. Expert evidence could be rebuttal of complainant's evidence in the form of affidavits by doctors willing to give evidence in defense.

Written Arguments[7]

Q46. How to file written arguments?

Ans: Written arguments should classify disputed and undisputed points. Then put medical scientific explanation of complication leading to disability and death supported by affidavits of expert witness, literature and case laws.

Appeal[7]

Q47. How to file an appeal?

Ans: Appeal must be filed after a complaint is decided against a doctor/hospital within the time limit, within thirty days of passing of the order from court to state commission or from state commission to national commission or from national commission to Supreme Court as the case may be.

Cross Appeal

Q48. What is cross appeal?

Ans: Both the parties are dissatisfied with lower court decision so complainant and OP both file appeal within the time limit, within thirty days of passing of the order from court to state commission or from state commission to national commission or from national commission to Supreme Court as the case may be. This is known as cross appeal and both the appeals are together.

Revision Petition[7]

Q49. What is revision petition?

Ans: Usually there are only appeals allowed in consumer courts. Concept of revision petition is restricted in same Consumer Commission as per CPA, 2019.

Execution Petition[7]

Q50. What is execution petition?

Ans: Usually if the order is not complied by OP then complainant can file an execution petition in consumer courts. This enforcement is known as execution petition. Proceedings are separately taken up and both the parties have to attend the hearing on appointed day and time. Only way to halt execution proceedings is obtain stay of higher court on the lower court order.

Miscellaneous Application[7]

Q51. What is miscellaneous application?

Ans: Matters related to errors in name of parties, not within proper jurisdiction, not within limitation period of 2 years, execution of orders, grant of stay on orders of lower court, interim relief's, removal of name from array of opposite party or adding name of extra OP or insurance company. All the matters, which are not, covered above need a miscellaneous application.

Duration of Proceedings[7]

Q52. How much time for disposal of case in consumer courts is prescribed?

Ans: Prescribed time limit is 90 days in cases allegations of deficiency in service and five months where goods require testing in appropriate laboratory.

Q53. Are fees prescribed for filing complaint and appeal?

Ans: Yes

Court Fees

Q54. How much fee for complaint in court and how much for appeal is prescribed?

Ans: As per the schedule of fees prescribed.

Inform Insurance Company[7]

Q55. How to inform insurance company?

Ans: In case there is an indemnity or hospital error and omission insurance policy in existence the doctor/hospital should inform the insurance company in writing immediately on a complaint being lodged by a patient with a copy of the complaint and notice received from the court.

HOW TO AVOID LITIGATION?

Factual Defenses[7]

1. A doctor must mention his qualifications, training, experience, expertise, etc. Support with relevant documents.
2. Doctor should mention his hospital's infrastructure facilities, special facilities, back-up support with documents.
3. Written evidence of consent of the patient/relative/attendant to assumption of inherent and special risks in the treatment.
4. Any proof that complainant has not come to the court with clean hands, i.e. he has suppressed material facts, e.g. previous illness, treatment, etc.
5. Inconsistence between notices sent directly or through consumer groups and the complaint made in the court.
6. Written evidence of consent of the patient/relative/attendant to assumption of inherent and special risks in the treatment.
7. Circumstances of the case, viz. emergency situation existed, lack of facilities (e.g. rural area), no responsible person accompanying the patient, no one to give history of patient's illness, etc.

8. Burden of proof of: (i) duty of care; (ii) breach of that duty; (iii) causation; (iv) damage, etc. is on the complainant.
9. Proof that treating doctor/hospital had sufficient knowledge, skill, care and infrastructure (rely/quote standard textbooks with attested photocopies).
10. Proof that there was consultation/treatment by patient from other doctor/other systems of medicine simultaneously.
11. Any other reasons/more than one reason/for occurrence of damage.
12. Any proof of contributory negligence, i.e. patient was brought late, in critical condition, complication existed beforehand, treatment was not adhered to, was lost to follow-up, etc.

Technical Defenses[7]

1. Proof that the medical service rendered was free of charge (now, this is applicable in certain situations only).
2. Concurrent adjudication in another court.
3. If the court does not have pecuniary/territorial jurisdiction.
4. If the complaint is time-barred.
5. A plea that since complicated issues are involved, which require recording of evidence of experts, hence case should be relegated to a civil court. But such a plea must be used at the beginning of the trial.
6. If the complaints are frivolous and vexatious and liable to be dismissed under Section 26 of the Act.
7. Inform your insurance company in writing with a copy of the complaint.

Prevention by Professional Indemnity[7]

Insurance Cover

Profession indemnity insurance is a must for every practicing doctor because it not only covers the claims of compensation awarded against doctor/hospital but also provides a sense of security to doctors that even if some negligence is proved the insurance company will take care of it.

Please clarify in detail about different premium rates of insurance in case of individual insurance, doctor/nursing home/hospital with qualified staff and unqualified but trained staff because when the insurance company is paying the compensation it usually makes such enquiries.

The insurance companies not only pay the compensation to other party but also arrange for the legal help from advocates. But please beware, there are reports that they sometimes join hand with other party for monetary gains justifying themselves that it is the insurance company and not the doctor who is to pay the compensation.

Here we must understand that only the money paid as compensation is not everything because our reputation also is at stake.

What can be the role of professional association like IMA: These bodies can play a major role in resumption of harmonious relations between doctor community and patients. With the help of media they can arrange seminars inviting doctors and common public where public can discuss their grievances and doubts with the doctors. This will establish an atmosphere of transparency and will improve trust and faith of

the patients for doctors they can establish their own grievances cell where complaints of patients can be addressed and if the concerned doctors have really erred then some sort of out of court settlement can be arranged. They can arrange TV shows and talk shows to discuss various issues, which confuse public hence leading to mistrust and anger. IMA keeps informing parents about various medical issues through its website. These efforts will go a long way in improving doctor–patient relationship.

Do's and Don'ts

1. Outside court settlement prior to receiving notice when you feel that you were not at all negligent.
2. Reply to legal notice
3. One should discourage outside court settlement after receiving notice
4. Do not sleep over the matter after receiving legal notice
5. Courts require evidence for diligence, prudence, care and caution in the alleged medical negligence case. Case papers explaining the process of disease, treatment and surgery, complications and their timely treatment needs to be properly explained as part of documentary evidence.
6. Legal technical defenses for doctors/hospitals are:
   a. Cause of action
   b. Pecuniary/territorial jurisdiction
   c. Non-joinder or mis-joinder of parties
   d. Free service given
   e. *No locus standi* as legal representative (LR)
   f. *Case subjudice* civil/criminal court
   g. The compensation claimed has been inflated or exaggerated for bench hunting of jurisdiction of the court/commission suitable to complainant.
   h. The complaint is time-barred
   i. The complaint is frivolous and vexatious and liable to be dismissed.
   j. Complaint has complicated issues involved; requiring recording of evidence of experts, hence complaint case should be filed in a civil court.
   k. Doctor is dead, i.e. action *personalis moritur-cum-persona*
   l. In case, there is indemnity insurance or hospital error and omission policy make insurance company a party to suit.

REFERENCES

1. Indian Penal Code, 1860.
2. Code of Criminal Procedure, 1973.
3. Indian Evidence Act, 1872.
4. Jacob Mathew vs State of Punjab (2005) 6 SCC 1.
5. Martin F. D'Souza vs Mohd. Ishfaq (2009) 3 SCC 1.
6. V Kishan Rao vs Nikhil Super Speciality Hospital (2010) 5 SCC 513.
7. Baldwa M, Baldwa V, Padvi N, Baldwa S. Legal Aspects of Medical Practice, CBS Publishers & Distributors Private Limited, Delhi, India, 2019.

Chapter
36

Advance/Bill not Paid

Hemant Gangolia

As said "Money is the root of all evil", the bills at the medical establishments are the main reason for the episodes of violence and litigations. The settlement and recovery of bills is a difficult situation and one needs more of social, managerial, manipulative and tactful skills rather than medical knowledge. It is imbibed in the minds of society and people that medicine being a noble profession, the job of doctors is to serve the people without the expectations of remuneration even though it may be appropriate to the medical services offered. Hence, they do not realize the value of medical services offered to them in terms of remuneration as well they feel it is to be bargained.

The monetary issues related to the medical practice can be seen at different levels of:W

1. OPD
2. Daycare surgeries and procedures
3. IPD
4. Surgeries
5. Emergencies
6. Sudden death

The solution to any issue is possible if one learns to apply the six words in our practice to all the levels as stated above. They are as follows:

1. **Anticipation** of the likely expense, patient's psychology, value of medical service, etc.
2. **Communication** of the estimated cost of treatment, consultation and follow-up charges.
3. **Documentation** of the communication more so in IPD, surgeries, daycare services.
4. **Limitations** in terms of infrastructure and facilities availability at one's set ups.
5. **Ethics** in terms of four principles of the medical ethics, viz. respect (autonomy), do good (beneficence), do no harm (non-maleficence), equality (justice).
6. **Introspection** in terms of our near and dear ones in the shoes of the patient.

Let us analyze the monetary issues at different levels.

OPD

a. The rates of the medical services available as per the facilities and infrastructure should be displayed at appropriate place in waiting room such as:
   i. Consultation
   ii. Follow ups

iii. Injections
iv. Dressings
v. BP checkup/diabetes sugar checkup
vi. Emergency fees
vii. Home visit, etc. as per the medical services offered at the OPD.

b. The stated rates as bills can be collected in advance before the consultation or after the consultation as per the setup of OPD at individual or group or corporate practice.
c. No free business at the OPD as doctors are always considerate while charging their fees throughout their medical practice. Still if there is unaffordable patient one should charge to minimum by giving concession to maximum possible. By offering free services one should not devalue oneself moreover by providing free services is not a defense in court of law if any litigation gets filed later on.

Clinical Establishment Act endorses the display of rates in the states where it is implemented and will in other states too after it get implemented there.

Daycare Surgeries and Procedures

a. After the explanation of the procedure, its complications, consent, the estimated cost of the procedure to be explained, the communication of which to be documented as well the possibility of percentage rise in the cost in view of any anticipated explained complications.
b. It is advisable to collect the estimated cost as a deposit with the settlement of the bill accordingly after the procedure as one cannot predict the worst mishap even possible with minor surgeries and procedures. Depending on the setting of the practice one may opt for the part advance payment and final settlement of bill on discharge but that carries the risk of bill recovery in case of mishap.
c. Usually there is an issue of so-called discount/concession as an Indian have the habit of bargaining, hence by keeping this issue at the back of the mind one can have bill on higher side and so-called concession offered gets appreciated by the patient. But once done same trend sets in, hence advisable to avoid it or otherwise at an individual call.

IPD

a. On admission the important job is the preparation of indoor paper, filling of consent forms and the explanation of the estimated cost of indoor treatment particulars and category wise for which the decision makers of patient should be very well defined. The documented communication of the estimated indoor treatment cost with the decision makers is the important aspect. Here again the various charges as bed, nursing, doctor, etc. can be displayed at appropriate place or as a leaflet with the indoor papers.
b. It is advisable to have the dedicated personnel for that and after the admission to do the counseling of the decision makers on day to day basis making them to pay the advances appropriately. The daily review is important and at the same time one should be a good listener to the grievances of patient as well of decision makers.

c. It has to be clearly explained and documented the payment modes in terms of deposit, advances, day to day payments, concessions if any, receipts as well the options of cash, cheques, DD, online, card payments. Any issue regarding the amount to be sorted out immediately and if need arises to be intervened by the in charge of the setup. In raising the bills the facilities and infrastructure has to be taken into consideration.

Surgeries

The same principles apply to the elective surgeries with regards to the documented communication of the estimated cost with the payment mode options in terms of deposits, advances and settlement bills.

Emergencies

The emergencies may be per se the emergency brought to the medical establishment or the emergency surgery arising out of the hospitalized patient. As per the Parmanand Katra vs Union Case Law, the patient has right to get treated in emergency state, that is doctor does not have the right to choose the patient in an emergency state, but has the right to choose the patient in a non-emergency state as per Regulation 2.1 of the Ethics of the MCI. Hence, in emergency there is huge issue of deposit and advance payment though if properly communicated can have the sufficient deposit by anticipating the probable outcome of the emergency state management?

The major issue arises in case of non-affordability of the patient where in spite of explaining the estimated cost one has to provide emergency care to the best of one's limitations and ability as per above case law and treat it. Try to stabilize and depending on the infrastructure to transfer the emergency by appropriate ambulance accompanied by appropriate personnel and to settle with whatever payment has received. It is advisable to issue the complete bill of the emergency management and to document the pending balance payment on the receipt after deducting the received amount.

Sudden Death

This is the most important, dicey, tricky situation very difficult to handle and the raised bill is most of the time the reason for assaults and litigation. Two scenarios arise:

a. In case of sudden death of stable patient on admission which is unexpected to both relatives of patient and doctor, the issue has to be handled tactfully with the appropriate communication.
b. In case of death of the serious or gasping patient on or after admission, the communication of the advance must be apt and reasonably placed.

In both situations the deposit is very important in view of the death as anticipated outcome, hence advisable to advance paid whatever is possible.

The last scenario is whether the medical establishment can withheld the release of the dead body against the pending bill payment. There are interesting case laws over the period when for the first time the above issue of not releasing the dead body in view of non-payment of the settlement bill went to Tamil Nadu State Commission where the decision went in favor of doctor. Any judgement comes with the reasoning. The reasoning being as there is contractual relationship between patient and doctor,

both have equal rights as per the Consumer Protection Act, in terms of doctor as service provider and patient to pay the fees for it. In this case the service was provided by doctor but the relatives of the patient has not paid the bill, hence the breach of the contract thereby the withholding the dead body against the pending bill was appropriate and justified.

In view of the similar case known as Hiranandani Hospital Mumbai case law, Mumbai High Court gave the judgment in favor of patient thereby the order to release the dead body with following reasoning. The reasoning being given that there are three wrongs involved, viz. legal, ethical and moral. Legally speaking the dead body can be held in view of contractual relationship, ethically cannot withheld as an alternate remedy available as well morally sentiments attached to the death in the family. Hence, dead body cannot be withheld in view of alternate remedy available which being to file a civil suit for the recovery of the bills but then it requires advocate, court fees and long waiting period therefore not advisable. But in such cases though the settlement bill has been refused, the bill to be stamped as pending and issued.

Hence, in such cases it is better to forget the bill thereby the most important aspect is the advance collection with appropriate counseling, documented communication with introspection and ethical considerations in raising such bills with the limitations of the medical establishment.

Ultimately all these difficult situations are going to stay and we have to learn to live with them, tackle them, as nicely as possible and reduce the stress. In the light of basic legal knowledge, let dispel these unfounded legal fears and do the right things in right directions.

KEY MESSAGES

1. Display of the rates of medical services available at medical/clinical establishment.
2. Documented communication of the estimated cost of the medical services.
3. The smart deposit/advance collection well anticipated one.
4. Dedicated personnel to counsel for regular advance deposit on day to day basis with an ear to their grievances.
5. To be watchful for deposits in emergency/serious/surgical cases.
6. Forget the bill in case of death if pending bill is refused in spite of counseling.

Section

8

Miscellaneous Topics

37. Professional Indemnity Policy: Which and Why?
38. Compulsory No-Fault Insurance
39. Issuing Medical Certificate
40. Treating Patient of Foreign Nationality
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Section Editors: VP Singh, Mahesh Baldwa

Chapter

37

Professional Indemnity Policy: Which and Why?

Sandeep Dankhade

INTRODUCTION

With the changing time, doctor–patient relationship is facing many negative changes. The enactment of Consumer Protection Act in 1986 and its subsequent application to medical practitioner has added fuel to the fire.[1]

Professional indemnity policy is meant for professionals to cover liability falling on them as a result of errors and omissions committed by them while rendering professional services.

GROUND FACTS ABOUT MEDICAL NEGLIGENCE

As per Salmond's Law of Torts, "negligence is the omission to do something which a reasonable man, guided upon those considerations which ordinarily regulate the conduct of human affairs, would do, or doing something which a prudent and reasonable man would not do."

Negligence is the breach of a legal duty to care. It means carelessness in a matter, in which the law mandates carefulness. A breach of this duty gives a patient the right to initiate action against negligence.

All medical professionals, doctors, nurses, and other health care providers are responsible for the health and safety of their patients and are expected to provide a high level of quality care. Unfortunately, medical professionals can fail in this responsibility to their patients and cause far-reaching personal injuries, and even death. Medical negligence occurs when medical professionals harm their patients by neglecting them, acting maliciously, or by providing substandard care.

At the outset it is important to remember that virtually every country in the world operates its own unique legal system. At common law, the issue of professional liability insurance is a subset of the law of negligence. Persons who offer medical advice and treatment implicitly state that they have the skill and knowledge to do so, that they have the skill to decide whether to take a case, to decide the treatment, and to administer that treatment. This is known as an ***"implied undertaking"*** on the part of a medical professional. Honorable Supreme Court of India has held that every doctor ***"has a duty to act with a reasonable degree of care and skill"*** . Doctors in India may be held liable for their services individually or vicariously. ***Doctors are not liable for their services individually or vicariously if they do not charge fees.*** Thus, free treatment at a nongovernment hospital, governmental hospital, health centre, dispensary or nursing

home would not be considered a "service" as defined in Section 2 (1) (0) of the Consumer Protection Act, 1986. But as this situation hardly exists as in government and private hospitals also, patients are given advantages of different government schemes indirectly. So almost all hospitals/doctors are liable for negligence.

A doctor can be held liable for negligence only if one can prove that she/he is guilty of a failure that no doctor with ordinary skills would be acting with reasonable care. An error of judgment constitutes negligence only if a reasonably competent professional with the standard skills that the defendant professes to have, and acting with ordinary care, would not have made the same error. One needs proper coverage in case medical negligence is proved in the court of law, depending upon speciality and number of cases he is dealing within day-to-day practice.

Types

Medical professional can opt for different types of policies as per their need. This is to be opted right from start of the practice.

1. Doctors indemnity policy
2. Doctors composite package policy: Along with doctor's individual indemnity policy, these policies also cover the loss or damage to the property.
3. Doctor's protective shield
4. Doctors' medical establishment policy: It gives protection to nursing home, hospitals or medical establishment.

These policies can be any one year (AOY) limit or any one act (AOA) limit.

In AOA limit, there may be various ratios like 1:1,1:2,1:4, etc. where the compensation limit will be divided into the number of Acts of negligence committed in that year as per the option given at the time of selecting policy.[2]

Requirements

1. Medical indemnity policy can be issued to an individuals who must be a Registered Medical Practitioner.
2. The Act for which claim is done should occur during the period of insurance, resulting in a claim made in writing against the insured.
3. The medical establishment shall be registered with competent authority as per the local rules and regulations or should have minimum facilities as per the requirement of insurers.
4. There should not be any wrong description, false representation or nondisclosure of any material information.

THE PREMIUM

The premium rate depends on the specialization (physician, surgeon and super specialist, etc.), and the nature of services provided by the insured and the number of qualified assistants, nurses, nature of equipment, etc. If the doctor wishes to cover unqualified staff working with them, an additional premium is required. It also depends on the limit ratio opted, i.e. AOA to AOY and the type of policy opted. It also depends on different aspects to be covered as per the protection shield.

SCOPE

It applies to claims arising out of bodily injury, illness and/or death of any patient caused by or alleged to have caused by an error, an Act of omission or an Act of commission during the professional service/duty. One must inform the insurance company, when you shift your nursing home or consulting room. Disclose your attachments with other hospitals or nursing homes, otherwise company may refuse to take liability arising in that places.[3]

EXCEPTIONS AND EXCLUSIONS

- Any Act committed in violation of any law/ordinance.
- Services rendered while under the influence of any intoxicants or narcotics.
- The third party public liability like accidents/injury in hospitals.
- Claims arising out of cosmoses like plastic surgery, cosmetic surgery, hair transplants, etc.
- Claims arising from any conditions related/associated with HIV/AIDS
- It does not cover liabilities arising out of personal injuries, libel, slander or any other form of defamation.
- It does not cover liabilities arising out of deliberate, willful or intentional noncompliance of any statutory provisions.
- Company may not be liable if the doctor practices in specialty other than the mentioned in the application form.
- The policies do not cover the liabilities caused by radiation or radioactive substances.
- Experimental treatments are excluded.

Advantages

- With the prior permission of insurance company, the legal expenses incurred by insured for defending the case are also payable.
- The insurer is bound to pay as per coverage, if those parties were liable to pay at the end. The non-joining of insurance company could not vitiate the trial. This was held in ***S. Panchori vs Dr K Pandey (1999) CP 332.***
- The company will always have the right to take over the conduct of the defense of any proceedings filed before the medical councils or any other criminal proceedings against the doctor connected with his professional capacity.

Benefits of Medical Indemnity Insurance

1. It is beneficial not only to the doctors or hospital but also to the patients and their dependents because the insurance company takes care of the compensation. ***[Jasbir Singh and others vs Pal Urology and others on 31 March, 2011.]***
2. ***Retroactive benefit***: This means that the insured will be covered for any professional Act or omission occurring during the period of insurance.
3. It would take care of the amount of damages against third party.
4. Scheme will also compensate on the principle of "no-fault liability "to give some relief in the case of death or permanent disablement of the patient.
5. The company will also pay the defense costs, which have a direct relevance to the claim.

Limitations

- No liability for any claim prior to the retroactive date specified in the policy.
- The insurers may arrive at compromised settlement without the legal establishment of negligence in a court of law, as it is cheaper, simpler and of least resistance to them rather than fighting out the case.
- It has been observed that if the patient or their advocate knew that the doctors are insured, then there are more chances of negligence suits.
- The employee shall take all reasonable precautions to prevent all accidents and shall comply with all statutory or other regulations.
- After the amendment of Consumer Protection Act in 2002 and 2019, the limits of compensation at district, state, and national levels have been enormously increased. The companies may be hesitant in indemnifying such a big amount or give only part payment especially if there are suits pending against the doctors.
- The company is not liable for the promise or payment made or given by the doctor for compromise without taking the insurance company in confidence.
- The amount of compensation may be restricted by the limit of indemnity you decide for.

Things to consider before buying professional indemnity:

1. Flexibility to choose your own lawyer.
2. Customizable premiums and cover.
3. Cyber and privacy protection.
4. Unlimited retrospective cover.
5. Run-off cover
6. Clinic indemnity cover.
7. Locum practice protection.
8. Emergency advances for defense trial.
9. Unintentional defamation cover.
10. Unintentional IP infringement cover.

Procedure

In the event of any notice from advocates or courts received by the insured doctor regarding compensation, it should be immediately forwarded to the policy issuing office with details and should co-operate with insurance company for defending the case on behalf of the insured.

Doctors are very soft target for any financial institutions. The role of insurance companies may not be controversial or questionable, but one must be alert and involve them whenever there is medicolegal difficulty. The professional indemnity may not protect from legal problems but it may turn out to be a protector for financial losses.[4] Thus, it gives mental peace over and above financial relief.

While signing a contract for professional indemnity, hospital insurance or risk management one must read in-between the lines. It is necessary that the system should be doctor- and patient-friendly and not insurance company friendly.

The insurance companies are coming with newer and newer policies for attracting the beneficiaries. It is desirable for a doctor or hospital to have full and maximum insurance in present era. The doctor's indemnity policy provides insurance protection

to the doctors against their legal liability to pay damages arising out of their negligence in the performance of professional duties.

Various organizations in India render indemnity insurance policies for medical practitioners. One can take services from the following:

- Human medicolegal consulting services or professional protection groups
- IMA National Professional Protection Scheme
- Professional Indemnity Policies by National General Insurance companies. There are various general insurance companies that offer indemnity insurance. Following are the top insurance providers that offer professional indemnity insurance in India:
  i. Tata AIG General Insurance Company
  ii. Reliance General Insurance Company
  iii. New India Assurance Company
  iv. ICICI Lombard General Insurance Company
  v. Bajaj Allianz General Insurance Company

The human medicolegal company or professional protection groups take care of all medicolegal problems and administrative problems, whereas routine insurance companies only indemnify consumer claims. Insurance can be taken from Indian Medicolegal Consulting Services Pvt. Ltd. One can contact the medicolegal company whenever one receives a notice from an advocate or a court or a warrant from the police. Also, the company can be contacted whenever one gets into a dispute with patients, when there is an administrative or hospital-related problem, or if an on-table death occurs during an operation or a procedure. They render services by providing insurance cover from a nationalized company such as National Insurance Company, Oriental, or United India Assurance Company. Guidance is given in maintaining medicolegal records. They also give valuable advice, inspect documents, prepare documents and give advisory support, and advocate support in all stages of consumer cases in all consumer forums and appeals till the Supreme Court. In criminal litigations and Medical Council of India actions, they help with advice and documentation.

The IMA National Professional Protection Scheme aims to protect the members and help them in case of harassment or litigation which may arise during the course of their professional practice. It also aims to provide legal aid to the members of the Scheme. Only life members of the IMA are eligible to become the members of the Scheme.

The concerned member shall inform the Honorary Secretary and State Representative of the Scheme as soon as the incident occurs. Incident includes notice from the advocate, or from any Legal Forum, or from the individual patients, or their relatives or intimation whereby the member gets information that a case has been registered with the police.

If the member fails to inform the concerned office bearers of the scheme about such an incident, the member will forfeit the right to enjoy the benefits of the Scheme for that particular case. The concerned member shall obey the instructions given by the management of the Scheme regarding the case. The scheme should not be made a party in the case because the Scheme is not an Insurance Company. Should the member be advised by the Scheme to file a counter petition or suit against the party concerned for damages and defamation, the member is bound to obey.

Professional indemnity policies by the National General Insurance companies cater to only consumer claims. They indemnify any Act committed by the insured who shall be a Registered Medical Practitioner giving rise to legal liability to third parties. The insured includes policy holding and his qualified assistants or employees named in the proposal. Policies are available for individuals, hospitals, and diagnostic centers. However, short period policies are not permitted. All claims have to be legally established, even as the company can opt for an out of court settlement which should be accepted by the claimant. Its jurisdiction covers all Indian courts. Calculation of premium depends upon any one accident (AOA) limit of 25%, 33.33%, 50%, or 100% selected for any one year (AOY) limit per indemnity. This means that if you take a policy worth Rs 50 lakh and if the AOA is 25%, you can claim compensation of only Rs 12.5 lakh per incident. The premium varies across diverse AOA categories. The indemnity is applicable only if the Act has been committed during the period of insurance commencing from retroactive date and continued thereafter without break.

According to a survey conducted in 2016 by the National Law University, Bangalore, there has been a whopping rise of 400% in cases related to medical negligence filed in consumer courts. Although only 10–15% cases are genuine, with doctors being found guilty, the medical personnel in the remaining 85% cases are left to defend for themselves. Thus, the need to be financially and legally insured is gaining velocity to protect the doctors if they are sued for mistakes and negligence. With increased awareness of the rights and a strong likelihood of garnering empathy from the judicial system it is imperative to have professional indemnity insurance for doctors that takes care of the legal and financial implications of the medical practice.

REFERENCES

1. Tiwari S, Baldwa M. What is Medical Negligence. In: Baldwa Tiwari S, Tiwari M, Shah N. (Eds). Legal Problems in day-to-day Pediatrics Practice, 2nd edition, Hyderabad. Paras Publishing 2010; pp 14–39.
2. Shah RM. Genaral Insurance Ready Reckoner, 23rd edition, Baroda: New India Assurance Company Ltd:2005;149–61.
3. Joshi MK, a-z Medical Law 2000, 1st edition, Ahmadabad, p. 289–92.
4. Tiwari SK, Baldwa M. Medical Negligence. In: Gupte S (ed). Recent Advances in Paediatrics, New Delhi, Jaypee Brothers: 2004;14:311–29.

Chapter
38

Compulsory No-Fault Insurance

Mahesh Baldwa

"No-fault" insurance pays immediately so it is patient-friendly and so also doctor-friendly! We cannot watch family lose everything after death of earning member. Hence this insurance.

INTRODUCTION

The reach of masses to allopathic medical and surgical treatment is increasing with so many government Schemes like Ayushyman Bharat, RSBY, BPL related health insurance Schemes. Naturally, India with 1.3 billion population shall naturally have more number of medical accidents and mishaps causing complications needing costly treatment. Rarely some treatments may lead to fatalities and debilitating injuries to patients with comorbidities. India has already over-burdened judiciary. This may become one more source of a litigation explosion to already strained judicial machinery.

How Common is the Situation in Practice

In health care system deaths are common. ICU in health care is extremely expensive. So, death in ICU and health care becomes litigation prone. This leads to practice of defensive medicine. Doctors of health care cannot give their 100% potential to patient being under fear of litigation. This is written with an aim to pave way to make a new statute or law or legislate "No-fault" medical compensation law and indemnity insurance to cover for medical negligence, mishap, accident under law of tort. This will pave way for health care practice of vigilant, vigorous practice of medicine to save lives of critically ill till last ditch effort. Patients will receive full potential of health care team.

What will be the Immediate Steps if the Patient is Brought to You?

No-fault insurance will restrain doctors from practicing defensive medicine. They will be able to give 100% of their potential to sick and serious. No doctor shall refuse any patient for fear of litigation. Patient shall receive all the treatment which scientifically and medically patient deserves. The goals of medicine, as laid down in the Hippocratic oath, are founded on profound moral–ethical principles, which require healthcare providers to be committed to the mitigation of suffering, to uphold the primacy of life and to recognize their corresponding obligations.[1]

What are the Legal Provisions in that Particular Situation for Patients/Doctors?

The leading case on this matter is **Parmanand Katara vs Union of India**[2] and several other cases decided on this basis, the three judge bench of Supreme Court noted in writ filed by a public-spirited person in response to a news report of a scooterist who was knocked down by a car and died due to lack of medical treatment. Following the accident, the scooterist was taken to the nearest hospital, but was turned away and sent to another hospital 20 km away which was authorized to handle medicolegal cases. The scooterist died while he was being transported to the other hospital. Doctor is looked upon by common man as the only hope when a person is hanging between life and death but they avoid their duty to help a person when he is facing death when they know that it is a medicolegal case. Though a physician is not bound to treat each and every one asking his services except in emergencies for the sake of humanity and the noble traditions of the profession, he should not only be ever ready to respond to the calls of the sick and the injured. Doctors cannot choose a patient who comes in emergency.

What will be the Subsequent Steps in Management to Continue the Treatment or Refer the Patient/Inform the Police or Law Authorities

On such occasions medical profession is approached and if he finds that whatever assistance he could give is not sufficient really to save the life of the person but some better assistance is necessary—it is also the duty of the man in the medical profession so approached to render all the help which he could and also see that the person reaches the proper expert as early as possible."Preservation/saving life" and "duty of care" are established as absolute, non-negotiable and supreme constitutional obligations of the medical profession and the state.[2] The doctors shall inform police and law enforcing authorities as required after giving first aid.

1. Preservation of human life is of paramount importance.
2. Every doctor, at a government hospital or otherwise, has the professional obligation to extend his/her services to protect life.
3. There should be no doubt that the effort to save the person should receive top priority. This applies not only to the legal profession, but also to the police and other citizens part of the matter.

What are the Laws Applicable in these Situations and Long Drawn out Judicial Process which goes on and on?

The Indian Penal Code of 1860, The *Code* of *Criminal Procedure* 1973, Indian Evidence Act, 1872, law of limitation, 1963, Consumer Protection Act, 2019, Code of Civil Procedure, 1908, *Permanent Lok Adalat*, organized under Section 22(*b*) of The Legal Services Authorities Act, 1987, National Medical Commission Act, 2019 and similar laws unending maze of law.[3] Punishment in India starts moment law in put in motion against doctor and it goes on and on. The judicial process itself is a punishment. At present, the SC has 193 working days annually, high courts 210 days and trial courts 245 days a year. Another expert's calculation, if no new actions are filed, 324 years would be needed to clear the dockets at current speed, courts keep working. Law Minister Ravi Shankar Prasad in a written reply said 43.55 lakh cases are pending in the high court and out of these, 18.75 lakh cases relate to civil matters and 12.15 lakh

cases are criminal cases. As on 1st June 2019, pending cases in the Supreme Court were 58,669 cases. Roughly 3 crore cases in all courts in India are pending.

What are the Legal Provisions in World?

In world most countries have same legal provisions like India with faster judicial clearance of cases. This is because India has 1.3 billion population with more than 3 crore cases still pending to be heard, amazing! Only two countries have "no-fault"[4–9] systems. Sweden and New Zealand are maintaining "no-fault" systems. In New Zealand, there is no medical malpractice system but rather a publicly funded accident compensation scheme that bars suing for compensatory damages, and separate medical professional accountability processes.

Difficulty in introducing Reforms like No-fault

It must be considered that there is nothing more difficult to carry out, nor more doubtful of success, nor more dangerous to handle, than to initiate a new order of things. Any kind of reform has enemies in all those who profit by the old order system, and only lukewarm defenders in all those who would profit by the new order.[7]

No-fault Professional Indemnity

In its strictest form, the term no-fault provide for the payment for patients party for economic losses for by producing medical bills incurred to treat complications and lump sum immediate monetary compensation for disability, death arising out of professional medical treatment or surgery and restrict the right to sue doctors. Because high threshold no-fault systems restrict litigation, they tend to reduce costs and delays in paying claims.

By paving way for no-fault professional indemnity one does not depend upon broad judicial interpretation of medical negligence substituted many a times as *res ipsa loquitur* for a complication or disability, death arising out of medical accident or mishap in treatment or surgery are done away so also lengthy, unending, seemingly speculative, frustrating court proceedings to all litigants. No-fault indemnity insurance eliminates the incentive to inflate claims.

Are there Inadequacies or Paradoxes in Existing Laws?

Main Shortcoming of Existing Law

There are shortcomings of existing law of tort related to medical negligence litigations are discussed and the reason for its replacement for patients. It will promote amongst medical professional's transparency in reporting errors, mishaps, accidents so future corrective actions and learning from mistake will be possible. Under the current system trial under law of tort related to medical negligence is deterrent to reporting errors, mishaps, accidents. It also promotes blame game and shame. The day litigation starts doctors feel heat of punishment, which may or may not happen. Medical professionals laugh at colleagues who are caught in litigation but wish that let this not happen to them during their practice. Apart from financial and time consuming repercussion of litigation, litigations are emotionally and psychologically exhausting. The judicial discretion keeps stifling the standard of care from case to case basis and its application and final outcome. It appears that one is speculating rather than litigating.

The Law of Tort is Failing

Despite favorable results predicted from application of a tort system to the commission of wrongful conduct, fissures have appeared in the tort system, prompting criticism of the system and arguments for various systemic changes and tort-alternatives. "The law is failing. It is incomplete as a compensation device, terribly wasteful of legal and other resources, doubtful as a promoter of safety, the probable cause of significant socially and economically undesirable conduct, and generally unsuccessful as a mechanism for doing justice between injurers and victims."[3] In spite of the growing list of its actual and perceived shortcomings, the current tort system has survived, if only because no "sensible alternative" to the fault system has been presented and accepted.

Studies on Results of Doctor–Patient Litigation

From India: In one study from India revealed that it is easier to prove allegations of medical negligence against surgery and allied specialty as compared to medicine and allied specialty. Chances of proof of allegations of medical negligence against diagnostic specialty (radiology, pathology, biochemistry, etc.) are highest at 50% cases, followed by surgery and allied specialty with 34.48%, dentistry with 25% and with least chances of prove in medicine and allied specialty with only 18.18% respectively.[11]

From USA: But even when a case is dismissed, the road is typically long for both doctors and the patients suing. How long malpractice claims take to resolve, or what proportion of them actually end in a payment to patients is studied. For this study, they looked at more than 10,000 malpractice claims against US doctors closed between 2002 and 2005. They found that of all claims, about 55% resulted in an actual lawsuit. Of those litigated claims, more than half were dismissed by the court. And out of the rest, most were resolved before a verdict; less than 5% ended up being decided by a trial verdict. When there was a verdict, it went in favor of the doctor 80% of the time.

For doctors, the outcomes of claims varied by specialty: For example, internists were among the most likely to have cases against them dismissed in court. Pathologists and pediatricians were least likely: about 36% of cases against pathologists, and a little over 40% against pediatricians, were dismissed. Pathologists study laboratory test samples and are key in diagnosing diseases. If they seem to have missed something, there is going to be more scrutiny. The same may be true in cases against pediatricians because a child is involved.[12]

Why Litigations are Tiring both for Patients and Doctors?

In a study on malpractice claims against US doctors are often dismissed, and when they go to trial, the verdict is usually in the doctor's favor. "Most claims go in favor of the physician, and they take a long time to resolve, "What is killing was the length of time cases took to resolve—even when they were dismissed." It is hard on everyone—patient as well as doctors. On average, lawsuits dismissed against doctors in court took more than 20 months, and some resolved out of the court before a verdict took over 28 months. Cases that went all the way to a trial verdict typically lasted a few years: 39 months, on average, when it went in favor of the doctor, and close to 44 months when the patient won.[12]

Capping the Compensation is not a Solution if State has to Pay for Health Care Costs in USA

President Bush has strongly advocated for the imposition of a $250,000 cap on non-economic damages and an undisclosed cap on punitive damages for all cases of medical malpractice. He claims these measures would "curtail frivolous lawsuits, decrease insurance costs, and ultimately lead to lower healthcare costs and better care for patients." The President has directed much of his criticism at trial lawyers for their alleged pursuit of "frivolous" claims that drive up the federal government's health care costs by twenty-eight billion dollars a year and clog up the courts to the detriment of more deserving litigants.[13]

Litigations between doctor and patients based on law of tort as basis medical negligence are:[14]

1. Long drawn out in time frame, even in consumer courts both for patients as well as doctors
2. Costliest even in consumer courts both for patients as well as doctors
3. It appears as if instead of litigation they are in speculation

Usual Difficulties for Patient Party[14]

1. Finding a qualified medical malpractice lawyer
2. Convincing the Judges that the doctor was negligent at admission stage of case
3. Proving the doctor's negligence
4. Complicated medical evidence
5. Necessity of medical experts
6. High cost of litigation

Usual Difficulties for Doctors[14]

1. Disruption and distress of a trial to a doctor's practice and family life.
2. Paucity of time.
3. Monetarily and psychologically expensive.
4. Long-term stress due to psychic burden takes its toll in physical health.
5. Not able to understand shifting, stifling, wobbling and variable legal algorithm and paradigm.
6. Real consent, medical records are impeached. Tacit consent has no place.
7. The average litigation goes on from 3 to 5 years or more.
8. Emotionally it is consuming and exhausting.
9. The allegations made are intensely personal and derogatory.
10. Winning is better than losing, because it just looks a Pyrrhic victory even after win.
11. All these may force them to settle out of court

Proposal of 'No-fault' Medical Compensation Law[14]

It is always patients who suffer death, disability, disfigurement due to alleged medical negligence. Though all death, disability, disfigurement is not due to alleged medical negligence but most of the times, it is patients who suffer from preventable medical error may not indulge into litigation. Patient party suffers in silence. Hence, for all who receive medical treatment, whether they allege death, disability,

disfigurement due to medical treatment or not should receive "No-fault" claim from insurance companies. This is a social benefit, which they can choose relinquishing tort remedy under alleged medical negligence law. This will also lead to proactive reporting and learning from error committed by doctors. "No fault" medical compensation law should be promulgated to replace medical negligence under law of tort.

Identification of Medical Error and Accidents as First Step to Learn and Prevent

In 2016, Medical errors are found to be under-recognized cause of death. 10% of all USA deaths are now due to medical error. Medical error is the third highest cause of death in the USA. "To err is human" so are medical errors. According to the CDC in 2013, 611,105 people died of heart disease, 584,881 died of cancer and 149,205 died of chronic respiratory disease—the top three causes of death in the USA. The newly calculated figure for medical errors puts this cause of death behind cancer but ahead of the respiratory disease.[15,16]

Insurance is a Win-Win Strategy for both Patients and Doctors: Universal Insurance Coverage of Patients and Doctors

Insurance coverage for patient in form of mediclaim, RSBY, Ayushman Bharat and indemnity insurance for medical professional is becoming common in health care system in India. Ayushman Bharat is National Health Protection Scheme, which will cover over 10 crore poor and vulnerable families (approximately 50 crore beneficiaries) providing coverage up to 5 lakh rupees per family per year for secondary and tertiary care hospitalization. Ayushman Bharat National Health Protection Mission will subsume the on-going centrally sponsored schemes—Rashtriya Swasthya Bima Yojana (RSBY) and the Senior Citizen Health Insurance Scheme (SCHIS).[17]

Nature of Tort-based Medical Negligence Litigations Need Study and Re-look before its Replacement: Complex and Intricate Nature of Medical Science

Medical science has always been complex, ill understood by common people. Hence, an illusory standard was created for medical profession. The illusory standard for conduct for physician was never defined. Initially illusory standard was self-regulated in form of medical ethics. Later legal illusory standard was created. Legal standard was couched in negative words meaning what physician ought not to do. Violation of legal standard was labeled as negligence. Legal standard kept on changing. The legal standard was tested on basis of reasonability, responsibility, duty of care, proximity and what not. The degree of standard also varied from situation to situation, physician to physician, geographical area, social values, economic conditions, and so also judge to judge.[14]

What was always Medical Accident or Mishap is Mislabeled Legally as Negligence?

Tort law, a fundamental building block of every legal system, features prominently in mass culture and political debates, which was never codified leaving room for judicial discretion. Law of tort is not simply a collection of legal rules and procedures set out by legal judicial pronouncements, based on set of cultural responses to avert risks, injury, assignment of responsibility, compensation, valuation, and obligation.[14]

Medical Accidents versus Medical Negligence

There is a thin dividing line between medical accidents and medical negligence. In common parlance, 'accident' means an event that occurs without one's sight or expectation and in the same way law also adopts it. The word "accident" means occurring by mere chance. Accident occurs as unintentional, an unexpected acts. Sometimes further spontaneous downhill bad events continue to occur without any further acts or omissions leading to additional damages.[14]

Shift of Focus from Causation to Fault in Medical Negligence

Lately, in cases of negligence court instead of focusing on causation, began to see occurrence of fault as most important factor for tortuous actions. With this shift in focus, it became less necessary to restrict actions to categories, where fault has set to have occurred because of falling short of prevailing professional standard.[14]

The prevailing standard was "duty of care" is nebulous concept.

The law of negligence requires professional people to conduct themselves in a manner that confirms to certain prevailing standards of conduct. Also known as duty of care in conduct.

Before 1932, there was no such thing as a 'tort of negligence' in 1932, Donoghue vs Stevenson, Lord Buckmaster, Dissented saying, where will negligence end? Where does liability end? Expanding ambit of negligence like this could result in unlimited liability that would impede the progression.

Ever Increasing and Stifling Domain of Arbitrary Interpretation of Phrase "Use of Ordinary Care" with Respect to Medical Profession

Lack of precise legal definition "use of ordinary care" is fraught with subjective terminology as reasonability, rationality, and responsibility. The standards of care are nebulous, keep changing and drifting with scientific technological advances with respect to time, place and person.

Legal Uncertainty in Describing Precisely What 'Negligence' is?

The uncertainty in definition of negligence existed since its emergence. The development of law of negligence in the last hundred and fifty years provides a good illustration of adventurous nature of judicial discretion and adventurism. Therefore, interpretation of phrase "use of ordinary care" is left to judicial discretion kept changing. Medical practitioners who were duly qualified and licensed to practice by Medical Council also had to take test of "use of ordinary care" as per the interpretation of judiciary. Never medical profession was allowed to set a standard for themselves. Medical ethics has as such no legal force and applied selectively, when required.[14]

Being Qualified, Skillful, Experienced, Obtaining Real Consent and Medical Records and Documentation may not be Enough to Save from Alleged Medical Negligence

Earlier medical negligence judgments were related to conduct of medical care. Now it got extended to medical opinions, medical interpretation of clinical judgment and interpretation of blood and imaging reports. Not only that, it also extended Bolam's rule to medical opinion, advice and judgement also. All these years, Indian judiciary adhered to Bolam's rule encompassing defect, deficiency in conduct of medical care

only with respect to treatment. Suddenly it extended the rule to medical opinions and interpretation, complication, unexpected abnormal anatomy and physiology of patient causing mishaps and accidents. The "egg shell rule" blasted. The domain of consent meant what is written on consent form is real consent leaving tacit consent gasping. Samira Kohli judgment underlines "real consent". Anything beyond even for benefit of patient if not life-saving is not allowed. The matter related to diligent conduct of medical care is extending and widening scope. Scope is so wide that judiciary is expecting what cannot be contemplated by ordinary intelligence, interpretation and judgment of practitioner in treating the patient. The judicial interpretation finds faults in conduct with respect to delay in diagnosis, delay in investigating, misinterpreting reports, misdiagnosis, wrong diagnosis, which as a matter of fact is largely based on opinion of an average practitioner. The death, disability and expenditure incurred by patient party creates a bias in favour of patient party forcing judiciary judge the case much above the standards of average practitioner. Medical documents and records, if kept were on several occasions were considered tampered, manipulated, inadequate, meaningless. It also opened floodgates for what precautions were not taken from hindsight knowledge. Issue of hindsight knowledge is not easy. If not kept, meant no defense. Medical records related to retinopathy of prematurity shows judicial discretion in V. Krishnakumar vs State of Tamil Nadu[19] saying "hastily written general warning". Court said "We are not prepared to infer from 'informed about alarms signs' that the parents were cautioned about ROP in this case". "A rule of happening of complication less than 10% with respect to what" is applied. Court also said "We are thus satisfied that we are not looking at the 1996 accident with 2007 spectacles."

It may not be hindsight knowledge in Western countries and AIIMS in Delhi but its percolation and translation to practical knowledge and application as routine practice for average practitioner in rest of India. During the litigation the stands taken by doctors undergo legal posturing to meet legal requirement as per advice of lawyers. This legal advice of stifling, posturing by doctors to explain medical records create further weakness and medical records become foes.

So, what is the point in contesting alleged medical negligence and speculating a win?

Legal Wobbling of Standard of Care and Uncertainty of Opinion whether they are Breached or not

If the defendant is found to have a duty of care, what is the reasonable standard of care and was it breached is decided by judiciary? Usually what is the standard is matter of law but interpretation is left to judiciary. But was the standard breached? Is a matter of fact, which again is left to discretion of judiciary.[14]

Medical Accidents were Traditionally Always Dubbed as Alleged Negligence[14]

Medical accidents and mishaps being tried as alleged negligence all these years. What were accidents *ab initio* are for all these years labeled as acts of negligence. Medicine is highly regulated profession. At every stage there is competitive examination. After passing final examination one has to obtain license to practice. All practitioners have to conduct themselves within four corners of medical ethics. With so much of tight regulation the chances for medical professionals not to conduct as per standards sounds impossible. So, now whatever mishap causes death, disability or huge expenses in an attempt to save life is alleged and dubbed as negligence.

Why I say medical mishaps causes death, disability or huge expenses in an attempt to save life are nothing but accidents for following reasons:

Legislating "No-fault" medical accident claim tribunal: bane or boon.

Doctors should stay warned of the challenges facing the healthcare profession in keeping pace with the information age. Medicine has always been quick to adopt and adapt new technologies and many advances in care have been due to utilizing advances made in other branches of science. Traditional boundaries between private and professional life are becoming blurred and the potential for members to inadvertently fall into medicolegal traps is increasing. Delivering high quality communications with patients when something has gone wrong which is accidental be communicated in skillful manner to patient party. The objective of effective open communication when an error or accident happens if not reported and kept wrapped under the carpet, is meaningless. There is a risk of in such kind of such legislation by creating a 'tick-box' mentality, which does not support the intensely sensitive, personalized and patient-centered conversations. You can have the best individuals with the best intentions, but in the wrong environment they can succumb to what is the norm of wrapping under carpet—the truth about medical accident. Because there is no legislation which will compensate medical accidents hence it is dubbed as medical negligence to get the compensation.[14]

Legislating medical accident claim tribunal will not only help patient party to inform about serious injury or death created by medical accidents error, mishaps and complications but also set learning opportunities from near misses, which would work free from without keeping smoke screens helping doctors to achieve better patient safety. This will create win–win situation for doctors, hospital and patients without blame game. Medical accident claims will compensate victim for all medical accidents immediately. Insurance for all doctors and hospital shall be compulsory like Motor Vehicle Act and Workmen Compensation Act.

No-fault New Zealand in 1992: The 1992 reforms—compensable medical injury was defined as "medical misadventure", which was either "medical mishap" (a rare and severe adverse event) or "medical error" (in effect negligence). The 1992 reforms (unfairly) restricted access to compensation for those suffering medical injury as opposed to general injury. The restrictive definition also increased the possibility of litigation from those not covered under the scheme. Thus in 1992 reforms introduced fault (medical error) into the otherwise no-fault scheme but obliged to report all findings of medical error to the Medical Council.[20]

No-fault New Zealand in 2005: Prior to 2005, patients could obtain compensation for medical injury under the scheme by proving 'medical error'. Medical error in effect amounted to negligence and, as all findings of error were reported to the Medical Council, could result in punishment for doctors.

Swedish No-fault System, 1975—Patient Compensation Insurance (PCI)

The PCI was established in 1975 by voluntary contract between the county councils and a consortium of insurers, in order to preempt the threat of statutory expansion of tort liability, possibly to a form of strict liability.[21] Private practitioners entered into similar contracts and a voluntary contractual Pharmaceutical Insurance (PI) was established in 1978.

Why Medical No-fault Insurance?

New Zealand is small in population and state can compensate victims, but India has about 1/6th of world population. Hence, medical no-fault insurance is more suited to India. This is to provide money to cover to victims of medical mishaps as back up concept of legislating "No-fault" medical accident tribunal. Legal rule is that every individual undergoing treatment is responsible for own injuries suffered in while taking medical treatment and same be termed as an accident, regardless of who is at fault. Its objective is to reduce the number of medical negligence litigation related damage claims and universal coverage of medical professionals with indemnity insurance coverage. This will also weed out unqualified medical practitioners who because of their inability to take professional indemnity insurance will be exposed. No medical professional in country should be allowed to practice without professional indemnity insurance.[14]

No-fault

A kind of medical indemnity insurance that provides that each driver must collect the allowable amount of money from his or her own insurance carrier subsequent to a medical accident, mishap, negligence regardless of who was at fault.[14]

What is Medical No-fault Insurance?

In its broadest sense, no-fault insurance is any type of insurance contract under which insured are indemnified for losses by their own insurance company, regardless of fault in the incident, medical negligence, mishap, accident generating losses. A policyholder (and his/her patients) are not only reimbursed by the policyholder's own insurance company without proof of fault, but also restricted in the right to seek recovery through the civil-justice system for losses.[14]

What does No-fault Mean?

A no-fault medical indemnity insurance system, such as patient compensation, works by paying claims regardless of who is to blame for an alleged medical negligence, mishap, accident. This means that the insurance company pays patient compensation benefits no matter who is found to be at fault for an alleged medical negligence, mishap, accident that resulted in the patient injuries during treatment. This provides an important layer of protection for patient who does not need to go through the additional burden of proving their case before receiving benefits from court of law or tribunal.[14]

Description of no-fault systems: No-fault systems generally exempt individuals from the usual liability for causing body injury if they do so while treating patients when medical professionals no-fault medical "liability" insurance. The insurance covers bodily injury of the patient party caused by medical negligence, mishap, accident, regardless of who is liable under ordinary common law tort and rules. No-fault insurance has the goal of lowering premium costs by avoiding expensive litigation over the causes of medical negligence, mishap, accident, while providing quick payments for injuries or loss to patients. Further, no-fault systems often grant "set" or "fixed" compensation for certain injuries regardless of the unique aspects of the injury or the individual injured.[14]

Fault vs No-fault

Difference Between a No-fault Insurance System and a Fault-based One

This operates on a no-fault system, which means that it does not matter who is to blame for an alleged medical negligence, mishap, accident. Either way, the injured patient is paid out to insurance cover with respect to medical expenses, expenses for extended treatment, disability, disfigurement, death and also lost wages.

In fault-based claims find out who is to blame is crucial to receiving compensation. Patient parties involved in an alleged medical negligence, mishap, accident must prove the fault of an opposing party (medical practitioner and team) before any compensation payments will be made. The benefit to no-fault systems is that claims can be processed much more quickly given that there is no burden of proof or lengthy dispute over who bares blame. This helps victims receive money sooner and with much less hassle.[14]

"No-fault" medical accident tribunal shall draw and be similar in provisions of "no-fault" law existing even today.[14]

EXISTING "NO-FAULT" LAWS

1. Motor Vehicle Accidents Claims Tribunals

It works on similar principles, rules, regulations like motor vehicle accidents claims tribunals are operative on the basis of "no-fault" systems with usually a fixed schedule for compensation for various injuries.

Railway accidents claims tribunal is operative on the basis of "no-fault" systems with usually a fixed schedule for compensation for various injuries.

2. Workers Compensation Tribunals

Workers' compensation is a system of compensation which allows employees who are injured at work to obtain payment for lost wages, medical costs, and occupational rehabilitation expenses without regard to their personal negligence or fault.

3. Divorce Law

The term no-fault is also used colloquially in reference to a type of divorce in which a marriage can be dissolved on the basis of irretrievable breakdown or irreconcilable differences, without a requirement that either party proves that the spouse was guilty of any misconduct causing the end of the marriage.

4. Proponents of No-fault Insurance

Proponents of no-fault insurance argue that medical negligence, mishap, accident are inevitable and that at-fault medical practitioners are not necessarily higher risk and should not necessarily be punished; moreover, they note that the presence of liability insurance insulates reckless or negligent medical professionals from financial disincentives of litigation; also, protect injured patients.This will promote universal insurance amongst medical professionals. As such medical mishap, accidents dubbed as medical negligence are getting higher and higher numbers hence, no-fault systems may make more sense.

Replacing Tort of Medical Negligence with No-fault Legislations

The number of medical accidents, mishaps, alleged negligence causing fatalities and debilitating injuries have become the source of a litigation explosion that was straining and in some areas like consumer courts it is overwhelmingly the judicial machinery. Much legal thinking in academia is required to be devoted to the question of whether the tort system should be replaced with another method of allocating risks of loss from medical accidents, mishaps and alleged negligence.

Traditional Tort Liability versus No-fault Liability

A "traditional tort" liability system for medical negligence for recovery is governed by principles of provable negligence.

It is obvious that costs for in no-fault systems will be higher, which in turn shall escalate premium for indemnity insurance for particular speciality of medical professionals.

In the case of economic (medical and wage-loss) damages, most no-fault systems permit injured parties to seek recovery only for damages that are not covered by available mediclaim insurance benefits. In the case of noneconomic (pain-and-suffering) damages, most no-fault systems permit injured patients to seek compensation only in cases of exceptionally "serious" injury, which can be defined in either of two ways:

Extent of Coverage under No-fault Systems

Medical no-fault systems focuses solely on issues of compensation for bodily injury to patient arising out of medical treatment but could be extended to if medical professional additional premiums for alleged medical mishap, accident or negligence that damages patient then patient may recover compensation for medical treatment along with excess medical expenses for treating medical complications if any. Medical bills and lost wages that exceed threshold limits would not be reimbursed by indemnity insurance for which patients may choose traditional remedy of negligence under tort.

The amount of damages to be paid by the insurance company is limited to actual medical and rehabilitation expenses, lost wages and necessary expenses with a low maximum and for a limited period. In addition, an injured person can sue the negligent medical professional for medical costs above the amount of the insurance, pain, and suffering if the injuries required medical treatment or resulted in permanent injury, broken bones or disfigurement, or wrongful death.

Economics of Fault versus No-fault System

Just as the test of fault against standards of reasonable care was becoming confused with standards of near perfection, so did the final result depend too often upon the fortuitous assessment of the evidence or the fortuitous skill of lawyer. All seemed not only expensive but wasteful to the point of extravagance, as was demonstrated so clearly by the high proportion of funds which never reached the injured persons in respect of whom they had been collected. And there was the affliction of protracted delays in judicial system. More victims are paid, they do not have to prove fault from which massive savings result, and overall, everyone is better off. It is true that claims that every individual victim will be financially better off cannot be convincingly made. However, judged in the broad spectrum, the reforms provide a better set of arrangements than tort.

"No-fault" Medical Accident Claims Tribunal Needs to be Backed up by Universal Indemnity Insurance

All Registered Medical Practitioners insured with indemnity insurance. The benefits of no fault include rapid payment of all medical expenses in most cases, elimination of lawsuits except in cases involving lesser injuries, very serious injury or death, and elimination of extensive and costly investigation, proof of negligence, medical reports and depositions. Insurance companies and some court reform advocates who believe "no-fault" alleviates a clogging of the courts favor it.

How does No-fault Work in the Patient Compensation Context?

With the "no-fault" patient compensation system, benefits are paid out to injured employees regardless of fault. This means that there does not need to be the lengthy and expensive fight over who is to blame for the accident that led to the worker's injuries.

Patient compensation benefits can still be claimed, regardless of whether the accident was caused by faulty equipment, following of incorrect instructions by a subordinate medical staff, the negligence of a third-party or the carelessness of the employee under medical professionals himself.

Insurance companies need to indemnity allows us to provide "No-fault" the most flexible and adaptive support to doctor members, especially during times of rapid change happening in medicolegal spheres where all complications, errors, mishaps are being bundled as negligence, deficiency of service or unfair trade practice which neither helps doctors nor patients who keep litigating in courts to prove complications, errors, mishaps dubbed as negligence, deficiency of service or unfair trade practice.

We hope all the stakeholders shall pave way for legislative "medical accidents claim tribunal" for better "patient–doctor relationship" and "stress free", "non-defensive" medical practice.

Compulsory No-fault Insurance

In fact, the registration for medical practice is given when doctor opts for "no fault" insurance policy.

Summary, Conclusions and Suggestions

There are shortcomings of existing law of tort related to medical negligence litigations are discussed and the reason for its replacement for patients. It will promote amongst medical professional's transparency in reporting errors, mishaps, accidents so future corrective actions and learning from mistake will be possible. Current litigations related to medical negligence are apart from financial and time consuming repercussion of litigation, litigations are emotionally and psychologically exhausting.

Legislating medical accident claim tribunal will not only help patient party to inform about serious injury or death created by medical accidents error, mishaps and complications but also set learning opportunities from near misses, which would work free from without keeping smoke screens helping doctors to achieve better patient safety. This will create win–win situation for doctors, hospital and patients without blame game. Medical accident claims will compensate victim for all medical accidents immediately. Insurance for all doctors and hospital shall be compulsory like Motor Vehicle Act and Workmen Compensation Act.

Implementation of a comprehensive New Zealand-style no-fault system of compensation is far from becoming a reality in the India and other countries. However, small expressions of interest may proliferate in the stasis of the current tort system in which doctors are increasingly choosing to change professions in the midst of their careers rather than face the uncertainty of potential painful lawsuits and the decreasing profitability of their profession based on skyrocketing overhead costs, which in India with Ayushman Bharat shall be bourne by government only. The medicine as profession shall not be opted by young and intelligent. The trend is bad for future of medicine.

Future of Insurance Lies in "No-fault Compensation System"

A no-fault compensation system would address many of the injustices of our current malpractice system. It could offer an antidote to the poisonous specter of lawsuits that haunts hospital wards and harms the doctor–patient relationship. If done effectively, it could offer a path forward that is more dignified for the patients who suffer from medical errors and more navigable for the doctors who mean well.

REFERENCES

1. The Hippocratic Oath [Internet] [cited 2020 Jan 17]. Available from: https://en.wikipedia.org/wiki/Hippocratic_Oath. Accessed on 20 October 2021.
2. AIR 1989 SC 2039.
3. PIL: Why does Supreme Court work for only 193 days in entire year? [Internet] [cited 2020 Jan 17]. Available from:https://www.indiatoday.in/mail-today/story/pil-why-does-supreme-court-work-for-only-193-days-in-entire-year-1241141-2018-05-25. Accessed on 13th January 2020.
4. Harleston J. No-fault medical liability compensation system.available from: URL; https://www.cga.ct.gov/2003/olrdata/ins/rpt/2003-R-0386.htm.
5. Bogdan J, Medical Malpractice in Sweden and New Zealand: Should their Systems be Replicated here? Centre for justice and democracy, 21 :7, 2011.
6. Troyen A. Brennan and David M. Studdert, "No-Fault Compensation for Medical Injuries," *JAMA*, July 11, 2001, at 219, found at hpc.state.nm.us/UNM Library/Alternative Compensation Events/No-fault Compensation for Medical Injuries.pdf.
7. Essinger K, *The Swedish Medical Injury Insurance* (February 2009), found at http://www.patientforsakring.se/resurser/dokument/engelska_artiklar/Report_on_the_Swedsih_Medical_Injury_Insurance.pdf. Accessed on 13th January 2020.
8. No-fault Compensation in New Zealand: Harmonizing Injury Compensation, Provider Accountability, and Patient Safety, February 24, 2006 available on internet on 13-05-2020 at https://www.commonwealthfund.org/publications/journal-article/2006/feb/no-fault-compensation-new-zealand-harmonizing-injury. Accessed on 13th January 2020.
9. Bal BS. An introduction to medical malpractice in the United States. *Clin OrthopRelat Res* 2009 Feb; 467(2):339–47. doi: 10.1007/s11999-008-0636-2. Epub 2008 Nov 26. PMID: 19034593; PMCID: PMC2628513. Accessed on 13 January, 2020.
10. Machiavelli N. The Prince (1532), Ch. 6, transl. George Bull., Penguin Classics, fourth printing (1995), pg. 19.
11. Rasheed J. Original Research Paper: A Study of Medical Negligence Cases. *J Indian Acad Forensic Med*. Jan-March 2015, Vol. 37, No. 1.
12. Docs win most malpractice suits, but road is long. Available from: URL; https://www.reuters.com/article/us-docs-win-most idUSBRE84M11N20120523. Accessed on 13th January 2020.
13. Bush outlines medical liability. CNN.com. reformhttp://edition.cnn.com/2003/ALLPOLITICS/01/16/bush.malpractice/. Accessed on 13th January 2020.

14. Baldwa M, Baldwa V, Padvi N, Baldwa S. Legal Aspects of Medical Practice, CBS Publishers & Distributors Private Limited, Delhi, India, 2019.
15. Medical Errors are Third Leading Cause of Death in the US. Available from: URL; https://www.usnews.com/news/articles/2016-05-03/medical-errors-are-third-leading-cause-of-death-in-the-us. Accessed on 13th January 2020.
16. Understanding Clinical Error. Available from: URL; https://www.rcemlearning.org/modules/an-introduction-to-human-factors-and-patient-safety/lessons/section-1-clinical-error/topic/understanding-clinical-error/. Accessed on 13th January 2020
17. Ayushman Bharat is National Health Protection. Available from: URL; Schemehttps://www.india.gov.in/spotlight/ayushman-bharat-national-health-protection-mission. Accessed on 13th January 2020.
18. Donoghue vs Stevenson [1932] UKHL 100.
19. Krishna Kumar vs State of Tamil Nadu AIR 2015 SC P.2836.
20. New Zealand's 2005 'no-fault' compensation reforms and medical professional accountability for harm. New Zealand Medical Journal. Available from: URL; https://www.nzma.org.nz/journal/read-the-journal/all-issues/2010-2019/2013/vol-126-no-1371/article-wallis. Accessed on 13th January 2020.
21. Danzon PM. The Swedish Patient Compensation System: Myths and Realities. Review of Law and Economics 1994; 14:453–66.

Chapter
39

Issuing Medical Certificate

Kusumlata Singhal

INTRODUCTION OF SICKNESS AND FITNESS CERTIFICATES

Issuing medical certificate is one of the duties as well as privileges of a Registered Medical Practitioner. One of the duties of a Registered Medical Practitioner consists of issuing medical certificates. It is a matter of considerable responsibility and numerous doctors have come to grief with either the health authorities or the medical councils of the country over irregularities in this task of issuing medical certificates. Pressure from patients to issue certificates may be great, and refusal may be difficult. However, the doctor's conscience and good sense must guide him, as the consequences of carelessness may be severe.

The signing of blank forms and prescriptions is particularly dangerous, however convenient it may be in busy practice.

Sickness certificate is issued for the expected duration of illness. This is issued when the person is still sick and undergoing treatment. Whereas, fitness certificate is required by the patient to be produced at the time of resuming their duties once they are cured of the illness and are fit for the same. As the legal necessity of sickness and fitness certificates is required at every point of time when the person falls sick, the importance of its proper documentation and recording cannot be underestimated. Thus, all the RMPs should be familiar with and acquaint themselves with proper and correct method of issuing these certificates in proper prescribed formats and also the liabilities that arise from noncompliance of the legal requirements in issuing these certificates.

Objectives

The main objectives of issuing sickness and fitness certificate:

1. In schools and colleges to authenticate the sickness of the students.
2. In various organizations both private and government, to confirm the reason for absence from work.
3. For various insurance purposes, to decide the number of claims.
4. To excuse the attendance of the witness before a court of trial.
5. For sickness benefit as per the Employees State Insurance Act.
6. Medical fitness certificate at the time of start of some job.

Rules for Issuing the Certificates

1. Only registered medical practitioner is authorized to issue sickness and fitness certificates.
2. These certificates should be preferably issued on letterheads bearing the name, qualifications, registration number and address of the RMP and it should be in the prescribed format.
3. The certificate is to be issued to the patient himself or to the guardian who has already given consent for examination and treatment for the illness of the patient.
4. A physician must ensure that any statements made in these certificates are to the best of his or her knowledge, accurate, and based upon current clinical information.
5. The statements should not be untrue, misleading and improper in any way.
6. Before providing an opinion on a patient's fitness to respective work in present sickness, a physician must ensure that he or she has a complete understanding and accurate information about the patient's employment requirements.
7. A physician must not state that a patient has been under his or her care unless that is the case. The duration of the care should be indicated.
8. The duration of illness mentioned in the certificate should be limited to the period during which the patient was actually under care and observation of the practitioner.
9. The certificate should not be issued for inadequate and extraneous reasons and should not be based on the information supplied by any other person. The certificate must be accompanied by a brief resume of the case giving the nature of the illness, its symptoms causes and duration.
10. The practitioner should preserve with him a duplicate copy of the certificate issued, prepared in the same process with the original, at least for three years. Otherwise he should maintain a register with details of the certificate issued with serial number and the signature of the patient to whom certificate is issued.
11. If more than one copy of certificate is required to be issued, it is to be marked duplicate.
12. Medical practitioner can demand fees for issuing certificate, if not issued from free hospitals.
13. The practitioner should sign the certificate legibly at the end along with the registration number and also the signature/left thumb impression of the patient attested by him.
14. The certificate should pertain to the illness that is actually treated by the practitioner. If during the course of treatment of such illness, the practitioner comes across any other disease or ailment, which he has actually not treated (e.g. colour blindness noticed in a patient being treated for malaria or syphilitic chancre in a case being treated for accidental injuries) then that information should not be included in the sickness/fitness certificate without the expresses written consent of the patient. In such cases, the rules that are applicable for professional secrecy and privileged communication should be followed.

Issuing of medical certificates is an integral responsibility of a medical professional. Quite often, it is casually issued leading to its gross misuse amounting to even being considered as false certificate. Moreover, it indirectly violates the medical ethics and

is liable to be punished severely and may entail the cancellation of the registration to practice of the medical professional.

Medical certificates are legal documents. One cannot write not for medicolegal use.

Medical practitioners who deliberately issue a false, misleading or inaccurate certificate could face disciplinary action under the Indian Medical Council (Professional Conduct, Etiquette and Ethics), Regulations, 2002. Medical practitioners may also expose themselves to civil or criminal legal action.

Seeing the importance of the subject, every RMP is supposed to follow certain guidelines.

Guidelines for Issuing a Medical Certificate

1. The certificate should indicate the date on which the examination took place.
2. Indicate the degree of incapacity of the patient as appropriate.
3. Indicate the date on which the doctor considers the patient is likely to be able to return to work.
4. Be addressed to the party requiring the certificate as evidence of illness, e.g. employer, insurer, magistrate.
5. Indicate the date the certificate was written and signed.
6. Name, signature, qualifications and registered number of the consulting Registered Medical Practitioner should be mentioned.
7. The nature and probable duration of the illness should also be specified.
8. This certificate must be accompanied by a brief resume of the case giving the nature of the illness, its symptoms, causes and duration.
9. When issuing a sickness certificate, doctors should consider whether or not an injured or partially incapacitated patient could return to work with altered duties.
10. The medical certificate under normal circumstances, as a rule, should be prospective in nature, i.e. it may specify the anticipated period of absence from duty necessitated because of the ailment of the patient. However, there may be medical conditions which enable the medical practitioner to certify that a period of illness occurred prior to the date of examination. Medical practitioners need to give careful consideration to the circumstances before issuing a certificate certifying a period of illness prior to the date of examination, particularly in relation to patients with a minor short illness which is not demonstrable on the day of examination and should add supplementary remarks, where appropriate, to explain the circumstances which warranted the issuances of certificate retrospective in nature.
11. Under no circumstances, a medical certificate should certify period of absence from duty, for a duration of more than 15 days. In case the medical condition of the patient is of such a nature that it may require further absence from duty, then in such case a fresh medical certificate may be issued.
12. Record of issuing medical certificate.
    Documentation should include:
    a. Patient to put signature/thumb impression on the medical certificate.
    b. Identification marks to be mentioned on medical certificate.
    c. Medical certificate should specify the date of issue, for which certificate given.

d. The level of incapacity (i.e. unfit for work, light duties, etc. within scope of practice).
e. Signature/thumb impression of patient

13. An official serially numbered certificate should be utilized.
14. The original medical certificate is given to the patient to provide the documentary evidence for the employer. The duplicate copy will remain in the medical certificate book for records.
15. The records of medical certificate are to be retained with the doctor for a period of 3 years from the date of issue.
16. It is, therefore, a misnomer to state that medical certificate is "not valid for legal or court purposes" and should be avoided. Registered medical practitioners are legally responsible for their statements and signing a false certificate may result in a registered medical practitioner facing a charge of negligence or fraud.
17. The certificate should be legible, written on the doctor's letterhead and should not contain abbreviations or medical jargon.
18. The certificate should be based on facts known to the doctor.
19. The certificate may include information provided by the patients, but any medical statements must be based upon the doctor's own observations or must indicate the factual basis of those statements. The certificate should only be issued in respect of an illness or injury observed by the doctor or reported by the patient and deemed to be true by the doctor.
20. Avoid issuing certificate for diseases which you are not treating or trained to treat.
21. Never issue with date on which you are on leave.
22. In case of indoor patient never ever show the days of admission more or less than actual. Date and time should be specified.
23. Write full name of the patient, as per record of your hospital.

Format of Certificate Required for Interview or Joining Some Job

The certificate must be from the Medical Officer or any rank above it from any Central/State Government Hospital/Dispensary/Medical College, must be brought by the candidate at the time of interview.

CERTIFICATE OF MEDICAL FITNESS

1. Application Form No.: .....
2. Name of the Candidate: .....
3. Father's Name: .....
4. Mother's Name: .....
5. Sex (Male/Female): .....
6. Height: .....
7. Weight: .....
8. Identification mark: .....
9. Chest measurement: .....
10. Heart and lungs: .....
11. Piles, hydrocele, hernia, etc.: .....

12. Vision: .....
13. Colour blindness: .....
14. Hearing: .....

Certified that the candidate possesses the medical standards given below and is medically fit for the ..... profession.

Place: .....

Date: .....

Signature and designation with seal of the Authorized Medical Officer .....
..... with R. No.

Medical Standards:

Height: Not less than 1.5 m for male candidates and not less than 1.4 m for female candidates. Weight: Minimum 41 kg approximately for male candidates and 37 kg approximately for female candidates. Chest measurement: Not less than 69 cm. with satisfactory limits of expansion and contraction for male candidates. Heart and lungs: No abnormality. Hernia, hydrocele, piles, etc.: Presence of any of these is a temporary disqualification to be rectified before joining the course of study. Vision: Normal. Where defective, it must be corrected to 6/9 in the better eye and 6/12 in the worse eye. Eye should be free from congenital and other diseases. Hearing: Normal. Where defective it must be corrected.

FORMAT FOR MEDICAL CERTIFICATE OF SICKNESS

This is to certify that I ..... have personally examined Shri/Smt./Ku. .....s/w/d/o .....aged about ..... years, sex male/female, caste ....., occupation.....resident of ..... (whose signature/left thumb impression is verified as under). He/she is suffering from (disease) ..... and I have advised him/her ..... I do consider that absence of ..... days with effect from ....., i.e. from ..... to ..... is absolutely necessary for restoration of his/her good health.

Identification marks of patient:
1. .....
2. .....

Signature or left thumb impression of patient Signature and name of RMP
Registration No.
Stamp of designation and qualification

Date:

Place:

FORMAT FOR MEDICAL CERTIFICATE OF FITNESS

This is to certify that I ..... have personally examined Shri/Smt./Ku. ..... s/w/d/o ....., aged about ..... years, sex male/ female, occupation ..... resident of .... (whose signature/left thumb impression is verified as under) and found that he/she has completely recovered from his/her illness and is now fit to resume duties in government/private service with effect from ..... I also certify that before arriving at this decision, I have examined the original medical certificate and statement of the case on which leave was granted or extended and have taken them into consideration in arriving at my decision.

Identification marks of patient:

1. .....
2. .....

Signature or left thumb impression of patient

Date: ..... Name and Signature of RMP Registration No.

Place: ..... Stamp of designation and qualification

GUIDELINES FOR COMPLETING THE FORMATS

Sickness certificate: The following guidelines are suggested when completing a valid sickness certificate and Registered Medical Practitioner while issuing a certificate of ill health should mention following points:

1. The certificate should be filled in legible handwriting.
2. Two identification marks should be mentioned in detail. The marks should be preferably from exposed parts of the body. The exact description of the marks as regards the location, site, size, color, etc. should be mentioned.
3. The name of the RMP should be mentioned in full. The RMP who has examined the patient should only issue the certificate.
4. Name of the patient is to be written in full along with the age, sex and address.
5. The exact nature of illness should be mentioned.
6. Any use of short forms or abbreviations should be avoided. The nature of illness should mention the ailment for which the patient approached the RMP and which was being treated by him.
7. The expected duration in number of days to be mentioned in the sickness certificate. If the RMP is of the opinion that any further increase in duration of treatment is anticipated, then such a comment can be made.
8. The signature of the medical practitioner along with the name in legible handwriting, registration number, date, time and place of examination should be mentioned.
9. Signature/left thumb impression of the patient is always obtained in the presence of RMP himself.

10. If the patient informs the doctor that he was ill for last three days, which information the doctor is not in a position to verify, then he should mention such a fact as, 'as per the information provided by the patient, he was ill since (date). However, the duration of illness in the sickness certificate will be from the date on which the patient visited the doctor.
11. If preprinted stationery is used, a practitioner shall delete words which are irrelevant.

Fitness Certificate

The following guidelines are suggested when completing a valid fitness certificate and registered medical practitioner while issuing a certificate of ill health should mention following points:

1. The certificate should be filled in legible handwriting.
2. Two identification marks should be mentioned in detail. The marks should be preferably from exposed parts of the body. The exact description of the marks as regards the location, site, size, color, etc. should be mentioned.
3. The name of the RMP should be mentioned in full. The RMP who has examined the patient should only issue the certificate.
4. Name of the patient is to be written in full along with the age, sex and address.
5. The exact nature of illness should be mentioned. Any use of short forms or abbreviations should be avoided. The nature of illness should mention the ailment for which the patient approached the RMP and which was being treated by him.
6. The exact duration in number of days to be mentioned in the fitness certificate.
7. The date from which the RMP considers the patient to be fit to resume his duties should be mentioned.
8. The signature of the medical practitioner along with the name in legible handwriting, registration number, date, time and place of examination should be mentioned.
9. Signature/left thumb impression of the patient is always obtained in the presence of RMP himself.
10. If preprinted stationery is used, a practitioner shall delete words which are irrelevant.

Thus, these certificates should be drawn up with care and attention, with due sense of responsibility for opinion expressed in them.

Liabilities

1. Issuing of a false certificate is not only ethically wrong but also attracts the provisions of Indian Penal Code.
2. Section 197 of IPC: Whoever issues or signs any certificate relating to any fact knowing or believing that such certificate is false in any material point, shall be punished in the same manner as if, he gave 'false evidence'.
3. Issuing of false certificate by an RMP may lead to penal erasure of the name of the practitioner from the medical register.
4. Physician may be required to testify in proceedings involving disputes between an employer and the employee (i.e. the physician's patient) based on the sickness/

fitness certificate provided. Physicians can be summoned as witnesses in legal proceedings under oath, providing their clinical notes on a patient, in such proceedings where they may be examined and cross-examined by legal counsel.

5. Furthermore, based on their reports, physicians may be called to depose before any judicial or quasijudicial boards, tribunals, etc. in disputes, appeals before such tribunal proceedings, or to appear before a boards of arbitration under collective agreements. Carelessness in completion of these forms can have serious medico-legal implications for a physician.
6. If the patient suffers any damages due to inclusion of any untrue, incorrect, misleading information in the sickness/fitness certificate by the RMP the patient has the right to avail legal remedies by filing a civil suit.

Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002 including amendments up to October 2016 has changed the format as given below.

FORM OF CERTIFICATE RECOMMENDED FOR LEAVE OR EXTENSION OR COMMUNICATION OF LEAVE AND FOR FITNESS

Signature or thumb impression of patient .....

To be filled in by the applicant in the presence of the Government Medical Attendant, or Medical Practitioner.

Identification marks:

1. .....
2. .....

I, Dr ..... after careful examination of the case certify hereby that ..... whose signature is given above is suffering from ..... and I consider that a period of absence from duty of ..... with effect from ..... is absolutely necessary for the restoration of his health.

I, Dr ..... after careful examination of the case certify hereby that ..... on restoration of health is now fit to join service.

Place: ..... Signature of Medical Attendant.

Date: ..... Registration No. .....

(Medical Council of India/State Medical Council of ..... State)

Note: The nature and probable duration of the illness should also be specified. This certificate must be accompanied by a brief resume of the case giving the nature of the illness, its symptoms, causes and duration.

Chapter
40

Treating Patient of Foreign Nationality

Mahesh Baldwa

INTRODUCTION

Medical tourism is bringing patient of Foreign Nationality to doctors and hospitals. India is attractive and cheap tourist destination for foreigners for medical tourism where primary purpose is seeking treatment. In August 2019, the Indian government made it easier for foreigners to receive medical treatment without necessarily applying for a medical visa. These initiatives by Indian government will help Medical Tourism market to reach around $9 billion in 2020. Furthermore, the major reason for foreign tourist to choose India is because, it boasts 38 hospitals accredited by the Joint Commission International.[1]

HOW COMMON IS THE SITUATION IN PRACTICE?

In 2017, according available figures with Ministry of Tourism, as many as 96,856 foreigners have visited India on Medical Visa.[2] In 2019, The Union Home Ministry on recently in 2019 declared that foreigners visiting India can avail medical treatment, except prohibited organ transplant, in India, obtaining a medical visa. The ministry said in a official document that indoor treatment may now be taken on primary (original) visa for pre-existing diseases, which the foreign national may have been suffering from even before entry into India and for various ailments that were in knowledge of that person.[3]

WHAT WILL BE THE IMMEDIATE STEPS IF THE PATIENT OF FOREIGN NATIONALITY IS BROUGHT TO YOU?

They fall in three categories:

1. Foreigners coming with exclusive purpose of taking medical treatment with medical visa.
2. Agent or website calling foreign patient for treatment to India—without medical visa.
3. Foreign tourist patients coming to medical doctor with unexpected sudden illness or emergency situation—with information to Foreign Regional Registration Office (FRRO)/Foreign Registration Office (FRO).

MEDICOLEGAL PROBLEMS OF TREATING PATIENTS WHO ARE FOREIGN NATIONALS

In case patient with foreign nationality alleges medical negligence against Indian hospital or Indian doctor, then what are remedies available to such patients?

1. Foreign nationality patients can sue in Indian doctor/hospitals in Indian courts both civil as well as criminal for alleged medical negligence.
2. Foreign nationality patients can sue in Indian doctor/hospitals in Indian courts in their home countries presumably some part of contract or communication occurred on internet or foreign territory:
   a. Doctor has outdoor clinic in foreign country
   b. Doctor/hospital has a branch office in foreign country where patient lives
   c. Doctor communicated on email with patient can assume cause of action taking place in home country
   d. Website lured patient can assume cause of action in home country
   e. Medical tourism agent soliciting patients for doctor/hospital.
3. Once Indian doctor/hospital is sued abroad if not attended, ex parte order shall be given by court of foreign jurisdiction. The decree is recognized, enforceable and executable by Indian courts against Indian doctor/hospital.
4. Provisions under the Civil Procedure Code on foreign courts and foreign judgements:
   a. Section 2(5): Definition of foreign courts
   b. Section 2(6): Definition of foreign judgements
   c. Section 13: When foreign judgement not conclusive
   d. Section 14: Presumption as to foreign judgements
   e. Section 44 and 44A: Enforcement of judgements
5. A foreign judgment is described and defined under Section 26 of the Civil Procedure Code 1908 (CPC) as a judgment of a foreign court of foreign jurisdiction. A foreign court, under Section 25 of CPC, means a court situated in territorial jurisdiction outside India and not established or continued by the authority of Indian government.
6. Execution of foreign judgment: A foreign judgment can be enforced in India in the following ways: For a judgment passed by a court in a reciprocating territory, by filing an execution petition under Section 44 (*a*) of the Civil Procedure Code 1908.
7. 'Reciprocating territory' means any country or territorial jurisdiction outside India which the central government may by notification declare to be a reciprocating territorial jusrisdiction for the purposes of Section 44 (*a*). A 'superior court' with reference to any such territory would mean such courts as are specified in the said notification.
8. A foreign decree is recognized and is considered final and valid in courts in India, unless the decree is legally flawed under Indian laws.
9. S. 13 of CPC is referred by Supreme Court in Brijal Ramjidas vs Govindram Gordhandas Seksaria (1943) 45 BOMLR 358[5], regarding foreign judgement is conclusive.
10. The legal and medical system in the India is helpful for medical tourism: The Indian judiciary system is good factor for promoting medical tourism. Medical profession is moral, ethical, unbiased and transparent ocupation. The legal system

respects human rights which is an important aspect to promote medical tourism. The destination country's human rights policies and history of medical law is one of the most important moral and ethical concerns regarding medical travel for everyone.

LEGAL PROVISIONS FOR FOREIGNERS COMING WITH EXCLUSIVE PURPOSE OF TAKING MEDICAL TREATMENT WITH MEDICAL VISA

They are given on website of FRRO/FRO. Web Address is https://boi.gov.in/content/frro-contact-list[6]. One can apply online or offline. Compliances also could be filed online and offline.

Medical Visa: What are the Laws Applicable for Foreign Patients?

Persons coming to India for medical treatment for serious illness are issued with this visa. They should produce in hospital following documents.

a. Copies of passport (photo page) and page indicating validity, bearing proper arrival stamp of Indian immigration.
b. Copy of letter from concerned hospital (should be eminent and recognized hospital) where treatment is being taken along with supportive medical documents/diagnostic test reports (with tentative period of treatment) from other country.
c. MX (Medical X) visa for caretakers and relatives accompanying patient.
d. Local proof of residence, i.e. copies of electric bill/telephone bill/leave and licence agreement or guest house/hotel accommodation proof letter and receipts.
e. If the applicant is admitted in the hospital, medical certificate to that effect, bearing photo of the applicant attested by the doctor.

Triple entry on e-Medical Visa. In the case of e-Medical Visa, extension may be granted up to 6 months on case to case basis on merits of each case by the FRRO/FRO concerned.

Medical Visa: Legal Procedures

A medical visa (MED Visa) is granted to a foreigner whose sole purpose is to seek medical treatment in established/recognized/specialized hospitals/treatment centres in India. In case the foreign national desires to avail treatment under the Indian systems of medicine, his/her case will also be considered.

Hospital authorities must share the documents issued by them, e.g. proper medical invitation letter, appointment letter, etc. as per the format given in Appendix II on the official email ID of concerned Indian Mission. Further, the hospital authorities should also provide letter to the foreign nationals (patients and attendants) for extension of visa and registration in the proper formats given in Appendix III and Appendix IV respectively for due submission to the FRRO/FRO concerned.

Visa to Attendant/Family Members: Further Legal Procedures

Attendants and family members of the patient coming to India for medical treatment may also be granted Medical Attendant Visa (MED X Visa) co-terminus with the 'MED

Visa' of the patient. However, minor children accompanying a parent, who has come for medical treatment on a Medical Visa, may be granted 'X-Misc.' visa co-terminus with the Medical Visa of the principal Visa holder.

Validity of Visa and Extension of Visa (in Respect of all Foreign Nationals other than Pakistan and Bangladesh Nationals)

The initial period of validity of Medical Visa (MED Visa)/Medical Attendant Visa (MED X Visa) may be up to a period of one year or the period of treatment, whichever is less. Medical Visa can be extended for a further period up to one year by the FRRO /FRO concerned on production of medical certificate from a government/ICMR (Indian Council of Medical Research)/NABH (National Accreditation Board for Hospitals and Healthcare Providers)/MCI (Medical Council of India)/CGHS (Central Government Health Scheme) recognized hospital. Any further extension will be granted only by the Ministry of Home Affairs.

Patient from Pakistan and Bangladesh

In the case of Pakistani and Bangladeshi nationals, visa validity, extension of visa and number of entries permitted, etc. will be governed by specific provisions.

Attendants of Patient from Pakistan and Bangladesh

In the case of foreign nationals other than Pakistan and Bangladesh nationals, not more than two persons (attendant or family member) may be allowed at a time for the grant of 'MED X' Visa. In the case of Pakistan nationals, only one attendant will be allowed. In the case of Bangladesh nationals, three attendants may be allowed.

Registration of Visa Procedures

i. Foreign nationals (other than Pakistan nationals) holding Medical/Medical Attendant Visa for a period exceeding 180 days will be required to get themselves registered with the FRRO/FRO concerned within 14 days of arrival in India.
ii. If the Medical/Medical Attendant Visa is valid for a period of 180 days or less, no registration would be required.
iii. Pakistan nationals holding a Medical Visa will be required to register themselves with the FRRO/FRO concerned within 7 days of arrival in India, irrespective of the duration of the visa.
iv. Pakistan nationals holding a Medical Attendant Visa will be required to register themselves with the FRRO/FRO concerned within 24 hours of arrival in India, irrespective of the duration of the visa.

Obligation on Hospitals/Hospital Administrators and Legal Procedures

Hotel keepers and others are required to submit details of the foreigners who have been provided with lodging/sleeping facility in their premises in the prescribed Form "C" (Appendix V). Hospitals/hospital administrators should write 'hospital' and 'hospital administrators' in place of ' hotel' and 'hotel managers' in this Form.

Appendix II

REQUEST FOR MEDICAL VISA

Visa Consular
Indian Embassy
(Address)
Request for Medical Visa

Dear Sir

..... (patient's name) has been advised to undergo ..... (diagnosis) at ..... (Name of hospital and place) by our Sr. Consultant, ... (consultant's name), Department of ..... (speciality).

The cost of treatment will be ..... (cost) and the duration of the treatment will be ..... (duration).

Passport details are given below for your kind reference.

Name of the Patient: .....

Passport number: .....

Name of the companion (attendant): .....

Passport number: .....

We request you to kindly issue visa to him/her and his/her companion (attendant).

Thanking you and looking forward to an early action from your side.

Yours sincerely

Authorized Signatory

Telephone number: .....

Fax number: .....

Email: .....

Appendix III

FOR VISA EXTENSION

To
FRRO/FRO
(Address)

TO WHOM IT MAY CONCERN

This is to certify that ..... (patient's name), ... (age/sex), ... (Nationality), holding passport number ..... is admitted in Bed No. ..... under my care for medical treatment at ..... (name of the hospital and place). He is accompanied by ..... (name of the companion/attendant).

They need to stay in ..... (place) for another ..... (duration) to complete their medical treatment. So, kindly extend their visas for ..... (duration).

This letter is issued for visa purpose only.

Details of visas granted to the patient and attendant

Details of visa	Patient	Attendant
Visa number		
Visa type		
Valid till		
Date of issue		
Place of issue		

(Name of the Doctor)
Sr. Consultant, Department .....
(Name of Hospital and Place)
Telephone number: .....
Fax number:
Email: .....

Appendix IV
Registration Formalities

To
FRRO/ FRO
(Address)

TO WHOM IT MAY CONCERN

This is to certify that ..... (patient's name), ... (age/sex), ... (Nationality), holding passport number ..... is admitted in Bed No. ..... under my care for medical treatment at ..... (name of the hospital and place). He is accompanied by ..... (name of the companion/attendant).

Kindly do their registration formalities.

This letter is issued for visa purpose only.

Details of the disease: .....

Details of visas granted to the patient and attendant

Details of visa	Patient	Attendant
Visa Number		
Visa Type		
Valid till		
Date of issue		
Place of issue		

(Name of the Doctor)
Sr. Consultant, Department .....
(Name of Hospital and Place)
Telephone number: .....
Fax number:
Email: .....

Appendix V

Form C

ARRIVAL REPORT OF FOREIGNER IN HOTEL/HOSPITAL

[To be completed in duplicate] online or off line
FRRO/FRO

Photograph

1. Name and address of the Hotel/Hospital: .....
   .....
   or other premises, where accommodation has been provided for reward/on payment .....
2. Phone/Mobile No. of the Hotel/Place of stay: .....
3. Name of Foreign Visitor in Full (as given in passport):
   .....
4. Date of Birth (DD/MM/YYYY): .....
5. Address in country where residing permanently: .....
   .....
   .....
6. Address/Reference in India: .....
   .....
7. Nationality: .....
8. Passport No.: .....
9. Place of issue of Passport: .....
10. Date of issue of Passport (DD/MM/YYYY): .....
11. Valid till (DD/MM/YYYY): .....
12. Visa No: .....
13. Date of issue (DD/MM/YYYY): .....
14. Valid till (DD/MM/YYYY): .....
15. Type of Visa: .....
16. Place of issue: .....
17. Arrived from: .....
18. Date of arrival in India (DD/MM/YYYY): .....
19. Date of arrival in Hotel (DD/MM/YYYY): .....
20. Time of arrival: .....

21. Intended duration of stay in Hotel (No. of days): .....
22. Whether employed in India (tick in appropriate box): Yes No
23. Purpose of Visit: .....

Medical/Health

24. Next destination/Proceed to: .....
25. Contact/Phone No. in India: .....
26. In country where permanently residing: .....

Note: Please ensure that no column is left blank/incomplete.
Photocopy of the photograph in Passport may be enclosed.

Manager's Signature
Seal Stamp of Hospital Administrator

LEGAL PROVISIONS FOR AGENT OR WEBSITE CALLING FOREIGN PATIENT FOR TREATMENT TO INDIA: WITHOUT SPECIFIC MEDICAL VISA

This category of foreigners taking medical treatment in India who are not tourist coming for tourism nor have come on medical visa but have come through the online agency who call foreigners for cheap and quality treatment on tourist visa. This is also known as gray medical tourism. This is nonemergency treatment without medical visa being issued by government of India.

Foreign patients being advised by hospitals or medical centres to get their visas converted into medical visas before getting admitted. The Home Ministry said a foreigner suffering from a minor medical condition, which needs only OPD consultation or treatment, may take treatment at any hospital of choice or treatment at any centre of choice on his or her primary visa. In case of indoor medical treatment of less than 180 days or up to the stay stipulation period, if any, stipulated on primary visa of a foreigner or the duration of his or her primary visa, whichever is earlier, a foreigner is permitted to take such indoor medical treatment except organ transplant. Serious ailments such as neurosurgery; ophthalmic disorders; heart-related problems; chronic liver and renal disorders; congenital disorders; gene therapy; radiotherapy; joint replacement, cosmetic surgery, bariatric surgery, and cancer treatments are some of the most sought out medical tourism procedures chosen by foreigners.

DENTAL TOURISM

Dental tourism means traveling abroad for affordable dental care, dental treatment, dental surgery or dental procedures, which are generally expensive in one's own country. Dental tourism forms 10% of the total Indian medical tourism which is projected to grow at 30%.[7] Most of first world countries do not cover dental treatments like root canal, fixed dental implants. They are extremely costly. India is favorite destination for dental treatment in months of November, December January when person of India origin, NRI, foreigners visit India during Christmas vacation. During this period they schedule dental treatment as well.

COMMERCIAL SURROGACY IS UNDER SCANNER

Now under scanner of commercial surrogacy, earlier as per medical visa regulations a foreign couple seeking surrogacy in India may apply for a Medical Visa and Medical Attendant Visa. The egg donor may apply for a Medical Visa and the companion attending on the egg donor may apply for Medical Attendant Visa. Any visa type other than Medical Visa for surrogacy purposes is punishable under Indian law. The foreign couple can be permitted to visit India on a reconnaissance trip on Tourist Visa, during which the notarised agreement between the couple and the prospective surrogate mother can be drafted, but no samples are to be given for surrogacy purposes to any clinic during such a preliminary visit. The Surrogacy (Regulation) Bill, 2019[8] was introduced by the Minister of Health and Family Welfare, Dr Harsh Vardhan in Lok Sabha on July 15, 2019. The Bill defines surrogacy as a practice where a woman gives birth to a child for an intending couple with the intention to handover the child after the birth to the intending couple. The offences under the Bill include: (i) undertaking or advertising commercial surrogacy; (ii) exploiting the surrogate mother; (iii) abandoning, exploiting or disowning a surrogate child; and (iv) selling or importing human embryo or gametes for surrogacy. The penalty for such offences is imprisonment up to 10 years and a fine up to 10 lakh rupees.

Agent or website calling foreign patients for treatment to India without registering with Ministry of Home Affairs (MHA)—so-called medical tourism—preferably ask them to register with MHA.

They do not take MHA prescribed visa care for foreign patients. But the ministry of home affairs in India has eased visa procedures for travellers to India who need medical treatment to diminish inconvenience involved. Foreigners with long-term visas of six months and more need not convert these to medical visas for treatment of trivial conditions that only require OPD consultation. For sudden illnesses that require hospital admission of less than 180 days, foreign nationals or their representatives have to approach the Foreigner Regional Registration Office (FRRO) and submit a medical certificate from a recognized hospital with information about the recommended treatment and its duration. The FRRO can grant a medical permit of less than 180 days against a fee. In such cases, the primary visa will not be cancelled. The government document said foreign nationals on valid visas were facing difficulties in getting medical treatment in India when they fell ill and were being asked to convert these before being admitted to any hospital.

Estimates of organized medical tourism without specific medical visa: The healthcare industry estimates that several thousand foreign patients are treated in private hospitals in India each year, with most coming from Asia and Africa without medical visa. They come because their home country is less developed as compared to India in healthcare.

REASON FOR MEDICAL TOURISM

India has highly qualified doctors and state-of-the-art equipment, and the treatments are approved by the World Health Organization (WHO) and the US Food and Drug Administration.[9] Hence, less developed countries consider it hub for medical treatment.

European or North American patients come because, whether it is for cataract or cardiac surgery, dental treatment, or hip replacement operations, treatment cost in

India is a fraction of what an identical procedure would cost in Europe or North America.

"Hip resurfacing costs about $5000 in India while it is about $15 000 in Europe," says Dr Vijay Bose, the surgeon who operated on the woman from Norwich last week. Escorts Heart Institute officials say a cardiac bypass in India plus air travel would cost $6000, compared with $23 000 in a private hospital in Britain or $30 000 in the United States.

Doctors here speak excellent English and patients can look forward to highly personalized care and most Western patients we get are covered by insurance or pay out of their own pocket. The Indian Healthcare Federation is urging Western insurance companies to introduce products with lower premiums for patients willing to travel to India for treatment. Hospitals say low cost is only one factor that makes India an attractive destination for British and North American residents.

On other side some hospitals also arrange tours to sites of interest and lessons in yoga or traditional medicine as "perks" in the health package.

Deterrent Factors

Despite the enthusiasm, Indian hospitals may not witness a deluge of Western patients. Currently the NHS does not fund British patients to go to India. It has told Indian hospitals that it cannot refer UK patients because flying time to India exceeds the three hours limit set for transferring patients.

Patient Without Specific Medical Visa

So, patients come unofficially through agents or website referrals. Some Indian hospitals have official OPDs in foreign countries for promoting cheap and quality treatments in India, indoor admission to the hospitals.

LEGAL PROVISIONS FOR FOREIGN TOURIST PATIENTS COMING TO MEDICAL DOCTOR WITH UNEXPECTED SUDDEN ILLNESS OR EMERGENCY SITUATION: WITH INFORMATION TO FRRO/FRO

Foreign tourists coming may fall sick and seek remedy for sudden unexpected sickness or emergency medical condition. Such patients may be treated on the similar basis as any other Indian national takes treatment since their primary aim was tourism and not taking treatment. The passport number, visa details, email id, permanent address in home country. One has to keep hard copy for outdoor and indoor admission, consent for each and every invasive procedure is required in case the treatment is questioned by any authority. They need to fill appendix V given below and report to FRRO/FRO. Address can be found on https://boi.gov.in/content/frro-contact-list.

Regulations Applicable to Foreigners in India

They are given on website of FRRO/FRO. Web Address is https://boi.gov.in/content/frro-contact-list.

The Acts dealing with entry, stay and exit of foreigner nationals in the country are:

i. Passport (Entry into India) Act, 1920[10]
ii. Foreigners Act, 1946[11]
iii. Registration of Foreigners Act, 1939[12]

Foreigners coming for staying in India for more than 180 days or specially coming for taking medical treatment under special visa category need to follow general Instructions for **Registration by the Foreigners**.[6]

Foreigners Registration in India excluding Pakistan and Afghanistan

All foreigners (including foreigners of Indian origin) (excluding Pakistan and Afghanistan) visiting India on long-term (more than 180 days) Student Visa, Medical Visa, Research Visa and Employment Visa are required to get themselves registered with the Foreigners Regional Registration Officer (FRRO)/Foreigners Registration Officer (FRO) concerned having jurisdiction over the place where the foreigner intends to stay, within 14 days of arrival.

Registration in India for Foreigners from Pakistan and Afghanistan

Pakistan nationals are required to register within 24 hours of their arrival.

Registration in India for Foreigners from Afghanistan

All Afghan nationals are required to register with the FRRO/FRO concerned within 14 days of arrival except those Afghan nationals who enter India on a visa valid for 30 days or less provided the Afghan national concerned gives his/her local address in India to the Indian Mission/FRRO/FRO. The Afghan nationals who are issued visas with 'exemption from police reporting' as well as exit permission provided they leave within the Visa validity period.

Passport Stamping Requirements

All the Indian Missions shall stamp the visas of the foreigners mentioned at (a) above (except Business Visa) to the effect, "registration required within 14 days from the date of arrival" in India. As regards (b) above, the Indian Missions should stamp the visas to the effect, "registration not required if each stay does not exceed 180 days". In case of Business visa, following endorsements shall be made: "Continuous stay less than 180 days—no registration", "if stay in a calendar year exceeds 180 days, registration required".

Responsibility of the Indian Host/Sponsor

i. To ensure good conduct of the foreigner during his/her stay in India and to inform the FRRO/FRO office in case of termination of business contract.
ii. To produce the foreigner in person at FRRO/FRO office within 24 hours in case of withdrawal of undertaking for the good conduct of the foreigner.

ARE THERE INADEQUACIES OR PARADOXES IN THESE LAWS?

Circumvention Medical Tourism

Like India was popular destination for surrogacy till 2019, similarly Ireland and Poland, two European countries with highly restrictive abortion laws, have the highest rates of circumvention tourism for abortion. There are also efforts being made by independent organizations and doctors, such as with women on waves, to help women circumvent draconian laws in order to access medical services. With women on waves, the organization uses a mobile clinic, board a ship to provide medical abortions in international waters, where the law of the country whose flag is flown applies.[13]

Similarly, Indians go abroad for sex selection and sex determination, organ transplant, particularly kidney and liver.

Similarly, following treatments are illegal in India even for foreign nationals so Indians go for medical tourism for:

1. Sex determination[14]
2. Abortion above 24 weeks[15]
3. Commercial organ transplant[16]
4. Commercial surrogacy

AMENDMENTS IN EXISTING LAWS

1. There is only Medical Visa law which is prevailing today. There has to be concrete law for treating patients from foreign countries. Amendments in existing laws to treat foreign national should be amended to price them higher for foreigners. The emphasis on health tourism is likely to distort the perspectives of health providers, promoting medicine as a purely commercial venture. Financial incentives specifically for hospitals treating foreign patients will mean the government would be indirectly subsidizing foreign patients. Looking to India's scares resources, some public health specialists caution that a government role in this activity would be detrimental to the public health sector. No foreigner should be allowed to seek treatment in public hospital. Only private hospitals should render services to foreign nationals visiting India with premium charged to them for treating their illness.
2. Alleged medical negligence should be tried in India and never in the home country of foreign national.
3. Ethical concerns: Due to heavy influx of medical travelers in developing countries like India, who have better spending capacity than the natives, it is observed that quality medical attention is being diverted away from the poor. This widens the gap between the wealthy and the less fortunate patients, especially in developing nations like India, which are favored destinations for medical tourists.

SUMMARY AND CONCLUSION

India is looked upon as hub for medical tourism since it is cheap with world class state of art infrastructure. Today merely Medical Visa laws govern medical tourism laws today. The subject matter not only relates to ministry of home affairs but also ministry of health. Financial incentives specifically for JCACO and NABH accredited five star state-of-the-art hospitals with world renowned senior experienced doctors in India treating foreign patients will mean the government would be indirectly subsidizing foreign patients treatment. Promoting medical tourism in public health facilities would be detrimental to poor patients. No foreigner should be allowed to seek treatment in public hospital.

Due to heavy influx of medical travelers in developing countries, who have better spending capacity than the natives, it is observed that quality medical attention is being diverted away from the poor. The ethical concern thus raised is that if action is not taken promptly, private healthcare providers will completely steer away from low paying local demographically majority of poor patients put all together. Profit

management, another major concern about medical tourism, is that the profits obtained from this industry are often seen to saturate within the rich and influential instead of trickling down and reaching the grassroot level support. This widens the gap between the wealthy and the less fortunate patients, especially in developing nations like India, which are favored destinations for medical tourists.

Alleged medical negligence can be tried in home country of foreign national and India, both. There should be clear-cut law to try all cases alleged medical negligence in India only. This puts doctors and hospital in quandary of litigations.

REFERENCES

1. Ghosh P (26 November 2019). "India's Medical Tourism Market". International business times. available from https://www.ibtimes.com/indias-medical-tourism-market-could-reach-9-billion-next-year-buoyed-low-cost-high-2874034. Accessed on 19.1.2020.
2. Medical Tourism: How cheaper costs are pulling foreign patients to India. Available from https://www.businesstoday.in/sectors/pharma/medical-tourism-how-cheaper-costs-are-pulling-foreign-patients-to-india/story/235525.html. Accessed on 19.1.2020.
3. Foreigners visiting India can avail treatment without obtaining medical visa: Available from https://www.business-standard.com/article/pti-stories/foreigners-visiting-india-can-avail-treatment-without-obtaining-medical-visa-govt-119083001408_1.html. Accessed on 19.1.2020.
4. Civil Procedure Code 1908.
5. Brijal Ramjidas vs Govindram Gordhandas Seksaria (1943) 45 BOMLR 358.
6. Bureau of Immigration. Available from: https://boi.gov.in/content/frro-contact-list. Accessed on 19.1.2020.
7. Dental tourism in India. Available from: https://tourismdentalindia.com/. Accessed on 19.1.2020.
8. The Surrogacy (Regulation) Bill, 2019. Available from: http://prsindia.org/billtrack/surrogacy-regulation-bill-2019. Accessed on 19.1.2020.
9. Rao P. India's medical tourism gets Africans' attention. Available from https://www.un.org/africarenewal/magazine/december-2016-march-2017/india%E2%80%99s-medical-tourism-gets-africans%E2%80%99-attention. Accessed on 19.1.2020.
10. Passport (Entry into India) Act, 1920.
11. Foreigners Act, 1946.
12. Registration of Foreigners Act, 1939.
13. Abortion Ship Campaigns. Available from https://www.womenonwaves.org/en/page/2582/ship-campaigns. Accessed on 19.1.2020.
14. Pre-Conception and Pre-Natal Diagnostic Techniques (PCPNDT) Act, 1994.
15. The Medical Termination of Pregnancy Act, 1971.
16. The Human Organs Transplantation Act, 1994.
17. Joint Commission on Accreditation of Healthcare Organizations. Available from https://www.jointcommission.org/en/ Accessed on 19.1.2020.
18. National Accreditation Board for Hospitals and Healthcare Providers. Available from https://nabh.co. Accessed on 19.1.2020.

Chapter

41

IMS Act Violation

[Infant Milk Substitutes, Feeding Bottles and Infant Foods (Regulation of Production, Supply and Distribution) Act]

Himabindu Singh, Apoorva

INTRODUCTION

- Infant malnutrition is a major cause of infant mortality, physical and mental handicaps.
- The National Family Health Survey (**NFHS**) data indicates that only 54.9% children are exclusively **breastfed,** in spite of advocacy and efforts by government and NGOs.
- UNICEF and WHO estimate that of the 10.9 million children who die, 2.4 million die in India alone. Most of these deaths are due to diarrhea, pneumonia and neonatal diseases. Promoting exclusive breastfeeding for the first six months and continued breastfeeding could contribute to the reduction in 16% deaths.
- Optimal breastfeeding practices in the first two years of life, especially exclusive breastfeeding for the first six months of life, can have the single largest impact on child survival of all preventive interventions with the potential to prevent 12–13% of all under-five deaths in the developing world or 1.4 million lives, according to the 2008 Lancet Nutrition Series.[1]

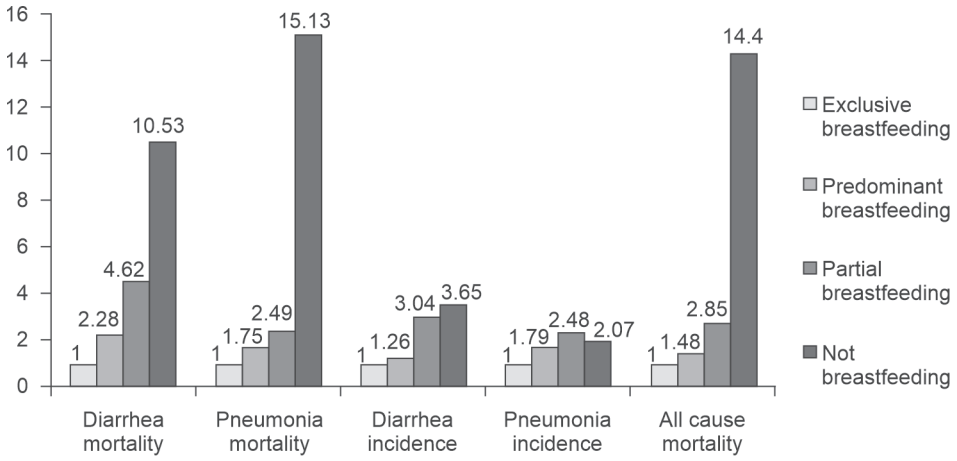


Fig. 41.1: Relative risk of not breastfeeding for infections and mortality compared to excessive breastfeeding from 0 to 5 months

- The influence on the growth and development on the *first 1000 days of the infant life is irreversible.* In these first 1000 days, 90% physical and brain development takes place.
- Infant Milk Substitute (IMS) Act is introduced to protect breastfeeding and the importance of mother's milk and infant and young child nutrition (IYCN).

WHY THERE IS A NEED FOR THE IMS ACT?

1. *To protect breastfeeding and infant and young child nutrition.*
2. Advertisement of infant formula has been shown to be extensive and persuasive compared to the dissemination of information on the advantages of mothers' breast milk.[2]
3. Unless there is a prescription by a registered medical practitioner for conditions like galactosemia, death of the mother during perinatal period or if the mother is on anti-cancer drugs, etc. infant milk substitutes should not be used.
4. There is a need of enforcement of law to curtail the aggressive marketing by the manufactures.

HOW COMMON ARE THE VIOLATIONS?

Violation of IMS Act is seen commonly in day-to-day practice. But most of the health workers are not aware of the Act and all the violations are not being reported to the concerned authorities. Due to under reporting of violations, the exact rates of violations in our country is difficult to estimate.

WHAT IS IMS ACT?

It is Infant Milk Substitutes, Feeding Bottles and Infant Foods (Regulation of Production, Supply and Distribution) Act, 1992 [IMS Act].

It provides for the regulation of production, supply and distribution of infant milk substitutes, feeding bottles and infant foods with a view to protection and promotion of breastfeeding and ensuring the proper use of infant foods and for matters connected therewith or incidental thereto.

The Infant Milk Substitutes, Feeding Bottles, and Infant Foods (Regulation of Production, Supply and Distribution) Act, 1992 and Amendment Act, 2003 (IMS Act) is India's biggest commitment in the interest of infants and young children.

The IMS Act bans any kind of promotion of infant formula, feeding bottles and infant foods for 0–2 years of children. It was enacted in 1992, came into force on Aug 1st, 1993. The Department of Women Development and Child Welfare (WDCW) government of India, formed a National Task Force for amendment and the Amendment Bill was submitted to Parliament in March 2002, passed by Parliament in June 2003 and came into force from Jan 1st 2004.

Some of the amendments made are:[2]

1. Pharmacy, drug stores and any association with health workers were included in Section 2, Clause (d)
2. In Clause (f), Section 2 after the age of 4 months was replaced by after the age of 6 months and up to 2 years.

3. Clause (j) was inserted in Section 2—promotion means to employ directly or indirectly any method of encouraging any person to purchase or use of infant milk substitute, feeding bottle or infant food.
4. In Section 3, Clause (a), for the words feeding bottles and infant foods were substituted.

Main Components

Act extends to all of India and stipulates that no person shall:[3]

- Advertise for the distribution, sale or supply of infant milk substitute's feeding bottles or infant foods.
- Give an impression or create a belief in any manner that feeding of infant milk substitutes and infant foods are equivalent to, or better than, mother's milk.
- Promote infant milk substitutes, feeding bottles or infant foods.
- Supply or distribute samples of infant milk substitutes or feeding bottles or infant foods gifts of utensils or other articles.
- Contact any pregnant woman or the mother of an infant to offer inducement of any of the above.
- Donate or distribute infant milk substitutes or feeding bottles or infant foods to any other person except to an orphanage.
- No person shall produce, supply or distribute any infant milk substitute or infant food unless every container contains the words "important notice" in capital letters, thereunder the following particulars:
  1. Statement "mother's milk is best for your baby" in capital letters.
  2. A statement that infant milk substitutes or infant food should be used only on the advice of a health worker.
  3. A warning that infant milk substitutes or infant food is not the sole source of nourishment of an infant.
  4. Its use and the proper method of its use.
  5. The instructions for its appropriate preparation.
  6. Warning against the health hazards of its inappropriate preparation.
  7. The ingredients used; the composition or analysis; the storage conditions required.
  8. The batch number, date of its manufacture and the date before which it is to be consumed, taking into account the climatic and storage conditions of the country; such other particulars as may be prescribed.
- No container shall:
  1. Have pictures of an infant or a woman or both; or have pictures or other graphic material or phrases designed to increase the saleability of infant milk substitutes or infant food.
  2. Or use on it the word "humanized" or "maternalized" or any other similar word; or bear on it such other particulars as may be prescribed.
- Every educational or other material including advertisements or material relating to promotion of infant milk substitutes, feeding bottles and infant foods whether audio or visual, dealing with prenatal or postnatal care or with the feeding of an

infant and intended to reach pregnant women or mothers of infants shall include clear information relating:

1. To the benefits and superiority of breastfeeding.
2. The preparation for, and the continuance of, breastfeeding.
3. The harmful effects on breastfeeding due to the partial adoption of bottle feeding.
4. The difficulties in reverting to breastfeeding of infants after a period of feeding by infant milk substitute.
5. The financial and social implications in making use of infant milk substitutes and feeding bottles.
6. The health hazards of improper use of infant milk substitutes and feeding bottles.
7. The date of printing and publication of such material and the name of the printer and publisher; such other matters as may be prescribed.

- No person shall use any health care system for the display of placards or posters relating to, or for the distribution of, materials for the purpose of promoting the use or sale of infant milk substitutes or feeding bottles or infant foods.
- No person who produces, supplies, distributes or sells infant milk substitutes or feeding bottles or infant foods shall make any payment to any person who works in the health care system for the purpose of promoting the use or sale of such substitutes or bottles or foods.
- No person, other than a health worker, shall demonstrate feeding with infant milk substitutes or infant foods to a mother of an infant or to any member of her family and such health worker shall also *clearly explain to such mother or such other member the hazards of improper use of infant milk substitutes or feeding bottles or infant foods.*
- No person, other than an institution or organization, engaged in health care for mothers, infants or pregnant women shall distribute infant milk substitutes or feeding bottles to a mother who cannot resort to breastfeeding and who cannot afford to purchase infant milk substitutes or feeding bottles.
- An orphanage may purchase infant milk substitutes or feeding bottles at a price lower than their sale price for the purpose of utilizing them in the said orphanage.

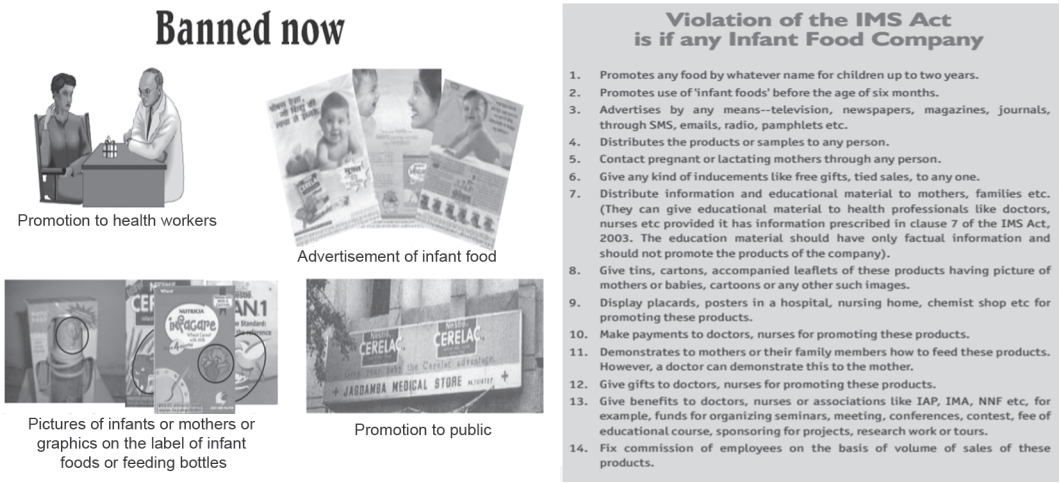

Banned now
Promotion to health workers
Advertisement of infant food
Pictures of infants or mothers or graphics on the label of infant foods or feeding bottles
CERELAC
JAGDAMBA MEDICAL STORE
Promotion to public
Violation of the IMS Act is if any Infant Food Company
1. Promotes any food by whatever name for children up to two years.
2. Promotes use of 'infant foods' before the age of six months.
3. Advertises by any means--television, newspapers, magazines, journals, through SMS, emails, radio, pamphlets etc.
4. Distributes the products or samples to any person.
5. Contact pregnant or lactating mothers through any person.
6. Give any kind of inducements like free gifts, tied sales, to any one.
7. Distribute information and educational material to mothers, families etc. (They can give educational material to health professionals like doctors, nurses etc provided it has information prescribed in clause 7 of the IMS Act, 2003. The education material should have only factual information and should not promote the products of the company).
8. Give tins, cartons, accompanied leaflets of these products having picture of mothers or babies, cartoons or any other such images.
9. Display placards, posters in a hospital, nursing home, chemist shop etc for promoting these products.
10. Make payments to doctors, nurses for promoting these products.
11. Demonstrates to mothers or their family members how to feed these products. However, a doctor can demonstrate this to the mother.
12. Give gifts to doctors, nurses for promoting these products.
13. Give benefits to doctors, nurses or associations like IAP, IMA, NNF etc, for example, funds for organizing seminars, meeting, conferences, contest, fee of educational course, sponsoring for projects, research work or tours.
14. Fix commission of employees on the basis of volume of sales of these products.

Fig. 41.2: What is banned under IMS Act

What is PROHIBITED and WHAT is Not as the IMS Act 1992 is Amended?

Following table provides in quickly understandable terms of what is the Amended Act 2003!!

Section	Promotional and marketing activities of baby food manufactures	Infant Milk Substitutes such as Lactogen–I, Lactogen-II, Nestogen-I, Nestogen-II, Lactodex-I, Lactodex-II, Amul Spray, Zerolac, Dexolac, ProSoyal, Simyl- MCT, Similac Neosure		Infant Foods such as Nestum, Cerelac, Farex, Weano, Veelac , Infacare, First Food, Dexrice, Easum, Junior Horlicks and other food products for consumption under two years of age.		Feeding Bottles any brand like Bonny Baby, Hello Baby, Wipro	
		PROHIBITED	NOT PROHIBITED	PROHIBITED	NOT PROHIBITED	PROHIBITED	NOT PROHIBITED
Section 3	Advertisements by any means including any notice, circular, label, wrapper, audio or visual transmission such as through television, radio, internet etc.	✓	✗	✓	✗	✓	✗
	Promotion for infants less than two years of age by any person	✓	✗	✓	✗	✓	✗
	Creating impression that a product is equivalent to better than mother's milk	✓	✗	✓	✗	✓	✗
	Encouraging the use and purchase of product by any person	✓	✗	✓	✗	✓	✗
Section 4	Distributing or supply samples by any person	✓	✗	✓	✗	✓	✗
	Contacting any pregnant or mother of an infant	✓	✗	✓	✗	✓	✗
Section 5	Offering benefits of any kind its promotion	✓	✗	✓	✗	✓	✗
	Donation and distribution of the product or any informational or educational material related to the product	✓	✗	✓	✗	✓	✗
Section 6 (2B)	Improper labeling of container and having pictures of infant or a women or both or a graphic on the label of the product	✓	✗	✓	✗	✓	✗
Section 7	Use of educational material to promote products.	✓	✗	✓	✗	✓	✗
Section 8	Promotion through a health care system like hospital, clinic, private practitioners, association of health workers, pharmacy, chemist shop.	✓	✗	✓	✗	✓	✗
	Use of health care system for display of play cards or posters or distribution of material related to product	✓	✗	✓	✗	✓	✗
	Making payment to a person working in a healthcare system for promoting the use of the product	✓	✗	✓	✗	✓	✗
	Demonstration of method of feeding of the product to a mother of an infant or any member of her family.	✓	✗	✓	✗	✓	✗
Section 9	Offering benefits or giving gifts to a health worker or to any member of his family	✓	✗	✓	✗	✓	✗
	Contributing or giving pecuniary benefits to a health worker or any association of health workers	✓	✗	✓	✗	✓	✗

Fig. 41.3: Prohibitions under IMS Act

- No person shall sell or otherwise distribute any infant milk substitute or infant food unless it conforms to the standards, specified for such substitute or food under the Prevention of Food Adulteration Act, 1954.

WHOM TO REPORT

IMS Act and its important components should be well communicated among all departments, health care workers, public and policy makers. It is also necessary to report violations in the interest of protecting infant and young child development.

The following are some of the forums for reporting in India:

1. Central Social Welfare Board (CSWB)
2. Women Development and Child Welfare Department (WDCW), GoI.

3. Breastfeeding Promotion Network of India (BPNI)
4. Indian Council for Child Welfare (ICCW)
5. Indian Academy of Pediatrics (IAP) and IYCF Chapter of IAP.

VIOLATIONS: PENALITIES

For those who violate this Act, government declared an imprisonment of not <6 months or up to 3 years and fine, not less than Rs 2,000 or up to Rs 5,000.

COMMITMENT OF IAP[5]

As per IAP resolutions, that any individual/association/alike (including "health care organization" and "health worker") **cannot** take sponsorship/favors/collaborate in **direct/indirect** ways; or be a part of such activity/transactions; or get involved in **direct/indirect** promotion from/of the manufacturers/companies/traders/distributors/their liaison/surveyors and alike who are dealing/concerned with products in purview of IMS Act.

Table 41.1: Indicative list of products under the scope of the Act

Name of Company	*Brand*	*Address*
Nestlé	Lactogen series, Nestogen, Nan series, Cerelac series, Nestum	Nestlé India Ltd. Nestle House, Jacaranda Marg, M Block, DLF City, Phase II, National Highway 8, Gurugram 122002, India. *https://www.nestle.in/*
Amul	Amulspray	Gujarat Cooperative Milk Marketing Federation, PO Box 10, Amul Dairy Road, Anand 388001, Gujarat *https://www.amul.com/products/amul-amulspray-info.php*
Raptakos Brett	Lactodex-1, 2, Zerolac	253, Dr Annie Besant Road, Worli, Mumbai 400030, India *https:/www.raptakos.com*
Danone Nutricia	Dexolac series, Nusobee, Aptamil, Nutritia Neocare LLP, Farex infant formula	Office No. 1, 3rd Floor, Level 3, The Centruim, Phoenix Market City, LBS Marg, Kurla West, Mumbai, Maharashtra 400070 *https:www.nutricia.com/*
Mead Johnson Nutrition Reckitt (Mead Johnson and Company, LLC)	Enfamil	3rd Floor, Piramal Towers, Peninsula Corporate Park, GK Marg, Lower Parel, Mumbai 400013 *https://www.meadjohnson.com/* Udyog Vihar Phase V, Sector 19, Gurugram, Haryana 122016 *https:/www.rb.com/offices/india/ https://www.meadjohnson.com/news/pressreleases/meadjohnsonnutrition-merger-reckittbenckiser-completed*

- BPNI's High Court lawyer works to analyze any reported complaints. Between 2003 and 2007, labels of infant foods and infant milk substitute like Cerelac, Nestum, Farex, Lactogen-1 and Lactogen-3 and baby care booklet "Hello Baby"

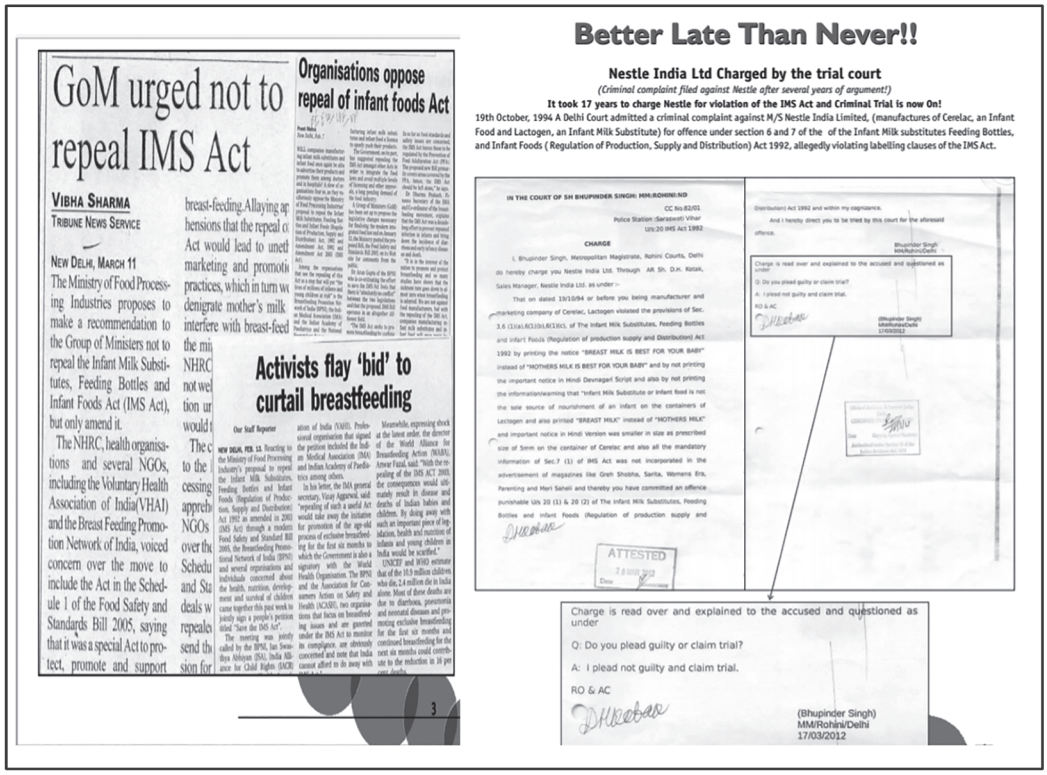

GoM urged not to repeal IMS Act
VIBHA SHARMA
TRIBUNE NEWS SERVICE
NEW DELHI, MARCH 11
Organisations oppose repeal of infant foods Act
Activists flay 'bid' to curtail breastfeeding
Better Late Than Never!!
Nestle India Ltd Charged by the trial court
(Criminal complaint filed against Nestle after several years of argument!)
It took 17 years to charge Nestle for violation of the IMS Act and Criminal Trial is now On!
19th October, 1994 A Delhi Court admitted a criminal complaint against M/S Nestle India Limited, (manufactures of Cerelac, an Infant Food and Lactogen, an Infant Milk Substitute) for offence under section 6 and 7 of the of the Infant Milk substitutes Feeding Bottles, and Infant Foods (Regulation of Production, Supply and Distribution) Act 1992, allegedly violating labelling clauses of the IMS Act.
IN THE COURT OF SH BHUPINDER SINGH: MM/ROHINI:ND
CHARGE
ATTESTED
Charge is read over and explained to the accused and questioned as under
Q: Do you plead guilty or claim trial?
A: I plead not guilty and claim trial.
RO & AC
(Bhupinder Singh)
MM/Rohini/Delhi
17/03/2012

Fig. 41.4: Implementation of IMS Act by various organizations and authorities

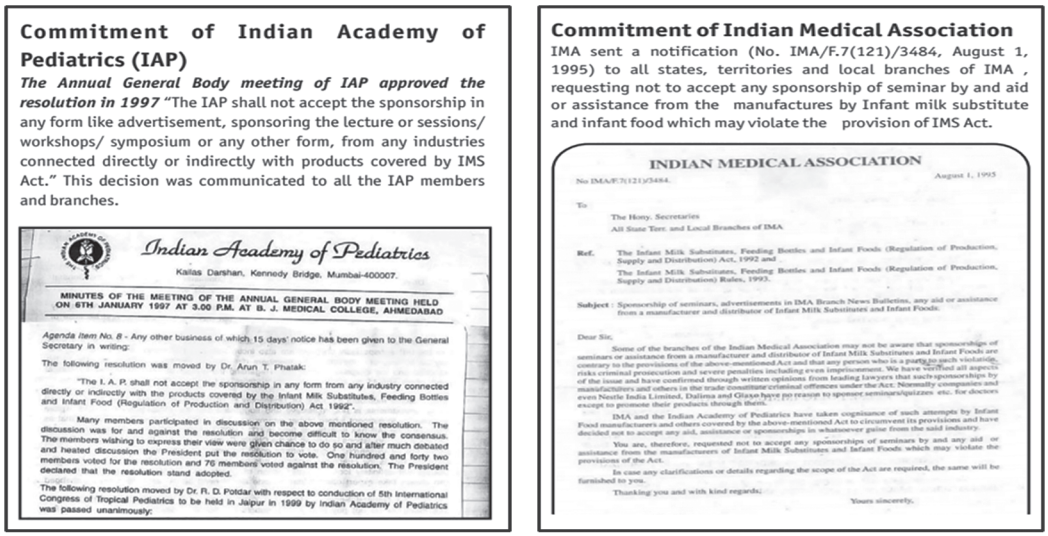
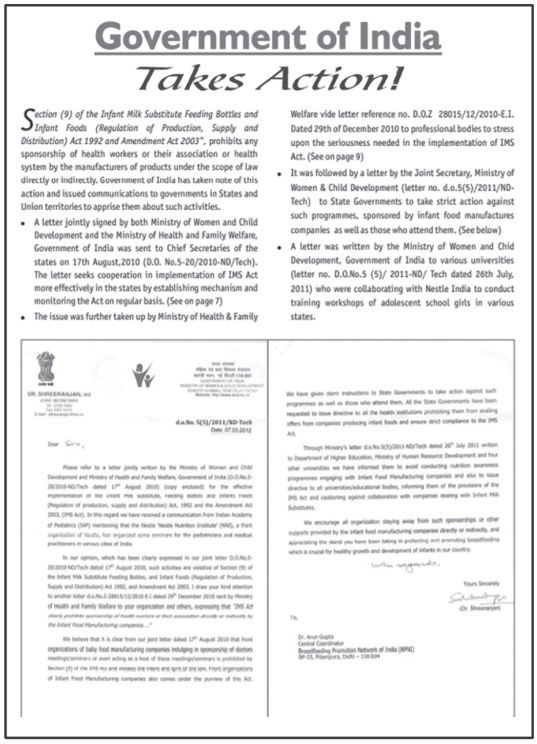
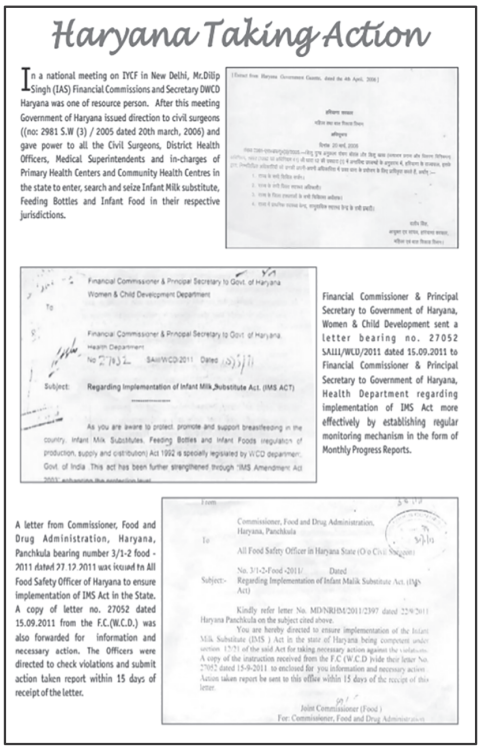

Commitment of Indian Academy of Pediatrics (IAP)
The Annual General Body meeting of IAP approved the resolution in 1997 "The IAP shall not accept the sponsorship in any form like advertisement, sponsoring the lecture or sessions/ workshops/ symposium or any other form, from any industries connected directly or indirectly with products covered by IMS Act." This decision was communicated to all the IAP members and branches.
Indian Academy of Pediatrics
Kailas Darshan, Kennedy Bridge, Mumbai-400007.
MINUTES OF THE MEETING OF THE ANNUAL GENERAL BODY MEETING HELD ON 6TH JANUARY 1997 AT 3.00 P.M. AT B. J. MEDICAL COLLEGE, AHMEDABAD
Commitment of Indian Medical Association
IMA sent a notification (No. IMA/F.7(121)/3484, August 1, 1995) to all states, territories and local branches of IMA , requesting not to accept any sponsorship of seminar by and aid or assistance from the manufactures by Infant milk substitute and infant food which may violate the provision of IMS Act.
INDIAN MEDICAL ASSOCIATION

Fig. 41.5: Implementation of IMS Act by various organizations and authorities


Government of India
Takes Action!
Section (9) of the Infant Milk Substitute Feeding Bottles and Infant Foods (Regulation of Production, Supply and Distribution) Act 1992 and Amendment Act 2003*, prohibits any sponsorship of health workers or their association or health system by the manufacturers of products under the scope of law directly or indirectly. Government of India has taken note of this action and issued communications to governments in States and Union territories to apprise them about such activities.
A letter jointly signed by both Ministry of Women and Child Development and the Ministry of Health and Family Welfare, Government of India was sent to Chief Secretaries of the states on 17th August,2010 (D.O. No.5-20/2010-ND/Tech). The letter seeks cooperation in implementation of IMS Act more effectively in the states by establishing mechanism and monitoring the Act on regular basis. (See on page 7)
The issue was further taken up by Ministry of Health & Family Welfare vide letter reference no. D.O.Z 28015/12/2010-E.I. Dated 29th of December 2010 to professional bodies to stress upon the seriousness needed in the implementation of IMS Act. (See on page 9)
It was followed by a letter by the Joint Secretary, Ministry of Women & Child Development (letter no. d.o.5(5)/2011/ND-Tech) to State Governments to take strict action against such programmes, sponsored by infant food manufactures companies as well as those who attend them. (See below)
A letter was written by the Ministry of Women and Chid Development, Government of India to various universities (letter no. D.O.No.5 (5)/ 2011-ND/ Tech dated 26th July, 2011) who were collaborating with Nestle India to conduct training workshops of adolescent school girls in various states.

Government Stops Sponsorship by
Nestle Nutrition Institute
Ban on baby food firms sponsoring medico meets?
PGI, Nestle Nutrition Institute Conference On Dec 10-12
ISPEN 2010 - 2nd Announcement

Fig. 41.6: Implementation of IMS Act by various organizations and authorities


Haryana Taking Action
In a national meeting on IYCF in New Delhi, Mr.Dilip Singh (IAS) Financial Commissions and Secretary DWCD Haryana was one of resource person. After this meeting Government of Haryana issued direction to civil surgeons ((no: 2981 S.W (3) / 2005 dated 20th march, 2006) and gave power to all the Civil Surgeons, District Health Officers, Medical Superintendents and in-charges of Primary Health Centers and Community Health Centres in the state to enter, search and seize Infant Milk substitute, Feeding Bottles and Infant Food in their respective jurisdictions.
Financial Commissioner & Principal Secretary to Govt. of Haryana
Women & Child Development Department
Financial Commissioner & Principal Secretary to Govt. of Haryana
Health Department
Subject: Regarding Implementation of Infant Milk Substitute Act. (IMS ACT)
Financial Commissioner & Principal Secretary to Government of Haryana, Women & Child Development sent a letter bearing no. 27052 SAIII/WCD/2011 dated 15.09.2011 to Financial Commissioner & Principal Secretary to Government of Haryana, Health Department regarding implementation of IMS Act more effectively by establishing regular monitoring mechanism in the form of Monthly Progress Reports.
A letter from Commissioner, Food and Drug Administration, Haryana, Panchkula bearing number 3/1-2 food - 2011 dated 27.12.2011 was issued to All Food Safety Officer of Haryana to ensure implementation of IMS Act in the State. A copy of letter no. 27052 dated 15.09.2011 from the F.C.(W.C.D.) was also forwarded for information and necessary action. The Officers were directed to check violations and submit action taken report within 15 days of receipt of the letter.
Commissioner, Food and Drug Administration, Haryana, Panchkula
All Food Safety Officer in Haryana State (O o Civil Surgeon)
Subject:- Regarding Implementation of Infant Malik Substitute Act. (IMS Act)

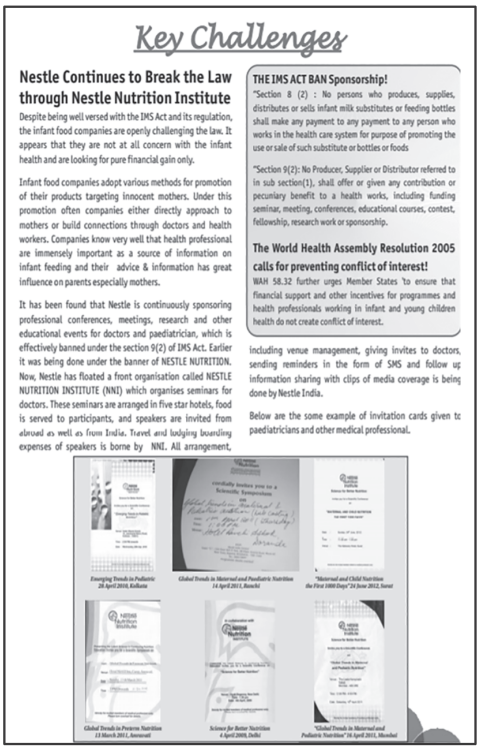
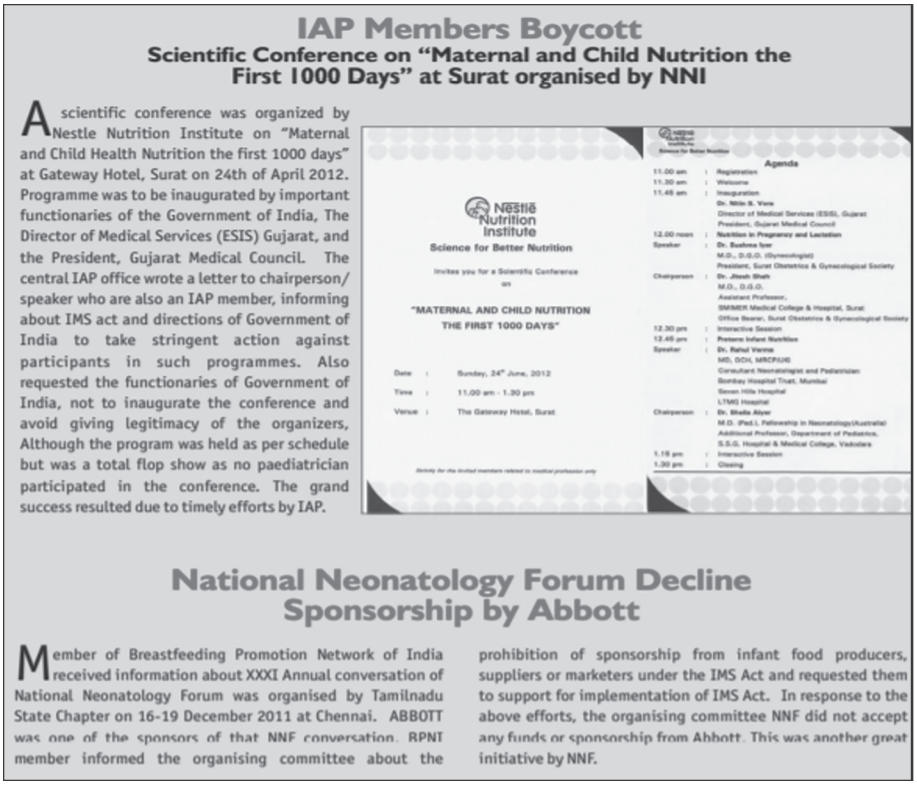

Key Challenges
Nestle Continues to Break the Law through Nestle Nutrition Institute
Despite being well versed with the IMS Act and its regulation, the infant food companies are openly challenging the law. It appears that they are not at all concern with the Infant health and are looking for pure financial gain only.
Infant food companies adopt various methods for promotion of their products targeting innocent mothers. Under this promotion often companies either directly approach to mothers or build connections through doctors and health workers. Companies know very well that health professional are immensely important as a source of information on infant feeding and their advice & information has great influence on parents especially mothers.
It has been found that Nestle is continuously sponsoring professional conferences, meetings, research and other educational events for doctors and paediatrician, which is effectively banned under the section 9(2) of IMS Act. Earlier it was being done under the banner of NESTLE NUTRITION. Now, Nestle has floated a front organisation called NESTLE NUTRITION INSTITUTE (NNI) which organises seminars for doctors. These seminars are arranged in five star hotels, food is served to participants, and speakers are invited from abroad as well as from India. Travel and lodging boarding expenses of speakers is borne by NNI. All arrangement, including venue management, giving invites to doctors, sending reminders in the form of SMS and follow up information sharing with clips of media coverage is being done by Nestle India.
THE IMS ACT BAN Sponsorship!
"Section 8 (2) : No persons who produces, supplies, distributes or sells infant milk substitutes or feeding bottles shall make any payment to any payment to any person who works in the health care system for purpose of promoting the use or sale of such substitute or bottles or foods
"Section 9(2): No Producer, Supplier or Distributor referred to in sub section(1), shall offer or given any contribution or pecuniary benefit to a health works, including funding seminar, meeting, conferences, educational courses, contest, fellowship, research work or sponsorship.
The World Health Assembly Resolution 2005 calls for preventing conflict of interest!
WAH 58.32 further urges Member States 'to ensure that financial support and other incentives for programmes and health professionals working in infant and young children health do not create conflict of interest.
Below are the some example of invitation cards given to paediatricians and other medical professional.

Fig. 41.7: Implementation of IMS Act by various organizations and authorities



IAP Members Boycott

Scientific Conference on "Maternal and Child Nutrition the First 1000 Days" at Surat organised by NNI

A scientific conference was organized by Nestle Nutrition Institute on "Maternal and Child Health Nutrition the first 1000 days" at Gateway Hotel, Surat on 24th of April 2012. Programme was to be inaugurated by important functionaries of the Government of India, The Director of Medical Services (ESIS) Gujarat, and the President, Gujarat Medical Council. The central IAP office wrote a letter to chairperson/ speaker who are also an IAP member, informing about IMS act and directions of Government of India to take stringent action against participants in such programmes. Also requested the functionaries of Government of India, not to inaugurate the conference and avoid giving legitimacy of the organizers, Although the program was held as per schedule but was a total flop show as no paediatrician participated in the conference. The grand success resulted due to timely efforts by IAP.

Nestlé Nutrition Institute
Science for Better Nutrition
"MATERNAL AND CHILD NUTRITION THE FIRST 1000 DAYS"
Agenda

National Neonatology Forum Decline Sponsorship by Abbott

Member of Breastfeeding Promotion Network of India received information about XXXI Annual conversation of National Neonatology Forum was organised by Tamilnadu State Chapter on 16-19 December 2011 at Chennai. ABBOTT was one of the sponsors of that NNF conversation. BPNI member informed the organising committee about the prohibition of sponsorship from infant food producers, suppliers or marketers under the IMS Act and requested them to support for implementation of IMS Act. In response to the above efforts, the organising committee NNF did not accept any funds or sponsorship from Abbott. This was another great initiative by NNF.

Fig. 41.8: Implementation of IMS Act by various organizations and authorities

from infant formula manufacturing companies were analyzed and found to violate the IMS Act. Legal action was brought against them.

- In 2010, an Annual conference for parenteral and enteral nutrition sponsored by Nestle Nutrition Institute was cancelled by the organizers when they received letters from BPNI and the India Ministry of Health and Family Welfare.
- In 2012, upon receiving a tip-off from BPNI, the regional Food and Drug Administration raided a Nestle factory, which was using inappropriate graphics targeting children under two years of age on their formula, specifically against the IMS Act. Nestle was fined after the event.
- In February 2016, the Indian Journal of Pediatrics blocked further circulation of their February issue, which contained infant formula advertising, when they received legal notice from BPNI regarding violation of the IMS Act.
- In 2019, the Health Ministry has come out strongly against violation of IMS Act by Nestle India through sponsorship of clinical trial in five hospitals which is prohibited under IMS Act.[7]

VIOLATION CASES

Case 1

Nestlé Nutrition accused of breaching IMS Act by sponsoring doctors' workshop Published on January 18, 2019.[8]

Union Health Secretary Preeti Sudan shot off a letter to the Ministry of Women and Child Development (WCD) alleging breach of the IMS Act by Nestle Nutrition Institute. Sudan, in the letter dated January 11 to the WCD, stated, "You may consider appointing an authorized officer for close monitoring and supervision of IMS Act implementation in the districts as per the provisions of the Act."

The trigger for this communication was a scientific program organized by baby food manufacturer Nestlé's global not-for-profit Nestle Nutrition Institute (NNI) on October 24, 2018 in Hotel Spice Treat of Dhule district in Maharashtra.

Sudan also sent an advisory to Health Secretaries of all states and the WCD on January 11 stating that the IMS Act bans sponsorship of health workers or their associations by companies manufacturing infant milk substitutes.

Case 2

ICMR response to Nestlé funded studies: In December 2019 ICMR has terminated the following studies for violating Section 9(2) of IMS Act.

1. Study of milk composition from adequately nourished and undernourished mothers.
2. Infant feeding practice and gut comfort: A multi-country cross-sectional observational study.

Both the above studies were funded by Nestec Ltd, a subsidiary company of Nestlé. Both the studies were terminated immediately.[4]

Case 3

A letter was issued in November 2010 by Ministry of Health and Family Welfare to PGIMER for violating Section 9(1) of IMS Act, as PGIMER was conducting a conference Indian Society for a parenteral and enteral nutrition: "Evidence-based Nutrition" in Collaboration with Nestlé Nutrition Institute. After the letter was issued the organizers have cancelled the conference.[4]

Case 4

In May 2016, British Life Sciences Pvt Ltd has blocked the advertisements of LF 100 in Indian Journal of Pediatrics as it was violating IMS Act.[4]

IMPLEMENTATION AND MONITORING OF IMS ACT

Role of Health Care Providers and Academic Organisations

- Educate people about the IMS Act.
- Involve local ANMs, ASHA and ICDS workers to reach to grassroot level.
- Hold public meetings, seminars, radio shows, TV shows.
- Establish links and spread the word. Monitor marketing and report violations.
- Violations on Cable TV like advertisements—report and ask operators to stop airing such things.
- Provide with addresses and contact details of reporting agencies.
- Start a campaign for 'Bottle-free villages' (Baby-friendly Community).
- Start protest campaign against any violating company.
- Pharmacists should not sell infant milk substitutes without a valid prescription from Registered Medical Practitioner.

Role of Parents

- They should have adequate knowledge on the importance of breastfeeding.
- Exclusive breastfeeding till 6 months is must, in fact it is the right of every child.
- After 6 months, start homemade complementary feeding, like cereals, pulses, vegetables, fruits.
- Breastfeeding the baby is women's right.
- The parents, families and public can become a big force in proper implementation and monitoring of IMS Act.
- They should be motivated to report violations of IMS Act.

Role of Policymakers

- The role of the government and policymakers does not end with the enactment of the law. They should take some bold steps to implement the policies and provisions of the Act.
- The Health Ministry, Women and Child Development Department, Human Resource Development Department should start promoting and supporting breastfeeding through TV and radio channels.
- There should be a separate portal to report the violations and that portal should be made public.
- Promotion of breastfeeding through the government media should be made on regular basis. Use of voice messages, social media, government apps, radio programs, etc. to promote infant and young child nutrition and provisions of IMS Act and reporting of violations can be very impactful.
- Unless stringent actions are taken against violators in short time frames, the IMS Act will not be taken seriously.

Key Points

- Infant and young child nutrition needs to be protected by promoting breastfeeding and home-based complementary foods.
- Awareness about IMS Act should be increased among health care providers and public.
- Reporting of violations of the IMS Act is the responsibility of all citizens in the interest of early child development.
- The rights of the mother and child should be protected by all organizations and government.

BIBLIOGRAPHY

1. Communication to The Indian Academy of Pediatrics (IAP) members Dated 12 August 2021.
2. https://www.bpni.org/national-policy-programme-4.
3. https://www.bpni.org/protecting-breastfeeding.
4. Robert Black. Maternal and Child Undernutrition: Global and regional exposures and health consequences. The Lancet 2008;371(9608):243–60.
5. The Hindu, January 2019.
6. Times of India, August 4, 2019.
7. The Infant Milk Substitutes, Feeding Bottles and Infant Foods (Regulation of Production, Supply and Distribution) Amendment Act, 2003. What has changed? *Indian Pediatrics* 2003;40: 747–57.
8. www.bpni.org/IMS Act.

Chapter
42

Medicolegal Issues in Acute Poisoning

Vivenanshu Verma

INTRODUCTION

The toxicology is defined as science which deals with knowledge of source, character and properties of poisons, their symptoms in the body, their pharmacological actions and treatment.

Poison is a substance introduced in the body to produce ill-effect, disease or death. It may be of any origin like synthetic, mineral, animal or vegetable. It may be introduced through any route like mouth, nostril, anus, vagina, ears, eyes, or by injection or inhalation.

HISTORY AND EVOLUTION OF POISONING AND ITS MANAGEMENT

Poisons are as old as mankind or perhaps even older. Their description can be found in the ancient Egyptian, Babylonian, Hebrew and Greek literature. Vedas (2000–1000 BC), especially Atharva Veda, furnish details about how to cure wounds, poisoning and snakebites. Poisons have been described in Atharva Veda, Kalpasthana, Chikitsasthana and Uttarasthana of the Shastras have described symptoms and antidotes of poisons in detail. Sushruta (350 BC) have described the procedures for incorporating poisons into foods, drinks, perfumes, medicine, bathing water, snuff or sprinklers. *Sushruta Samhita* written by Sushruta in 200–300 AD refers to poisons, snake signs and treatment of poisoning. In fact, the Indians were among the first to develop a secret service in the ancient world that used poison as a means of political assassination by *Vishakanyas. Vishakanyas* (poison damsels) were used to poison male targets by ingeniously taking advantage of the men's weakness for women. Frequently, poisons were concealed on a woman's body and delivered to the victim during amorous encounters. *Vishakanya* was in possession of a hollow ring that she used to poison drinks. *Vishakanyas* had toxic arsenic-infused mixture as ladies' cosmetic, wearing the toxic makeup during encounters with unfortunate victims. Alternatively, female poisoners won the trust of their victims by flirtatious means to gain the opportunity to blend poison into food or drink. Indians were also among the first, as early as 500 BC, to write about the forensic detection of poisoners by examining their personality traits.

Coroner's Act, 1811 was introduced by British in Kolkata and Mumbai and police investigations began in India then. The Indian Penal Code (IPC) came into existence in 1860 and Criminal Procedure Code in 1861. The Forensic Toxicology in India was

started by Dr Jaising P. Modi. For the first time in India in 1920, he was the one who wrote a book on Forensic Medicine and Toxicology. It was titled, *Medical Jurisprudence and Toxicology*. He is called the Father of Forensic Medicine in India. He described the Indian medicolegal experience for the first time in his book, which is still considered as a reference in all the medicolegal cases related to poisoning in Indian legal courts of justice.

Poison Information Centre and Poison Control Centre: In 1994, National Poison Information Centre was started at All India Institute of Medical Sciences, New Delhi. WHO has provided its software on poisons (INTOX) from where complete information about poison regarding its composition, diagnosis, clinical features and treatment is made available to public. Second centre was opened at National Institute of Occupational Health, Ahmedabad. New centres have also come up at Government General Hospital, Chennai, Industrial Toxicology Research Centre, Lucknow and Amrita Institute of Medical Sciences (AIMS), Kochi. The government of India plans to open more centres all over India. All these centres can be assessed by common public or medical community to know about nature and treatment of any poison. The Modern Medical Toxicology in India was started by Dr Vijay Vasudev Pillay. In 1995, he wrote the first ever Indian book devoted on *Modern Medical Toxicology*, which has become the medical reference. In 2004, He founded the Indian Society of Toxicology (IST), and established first Poison Control Centre in India at AIMS, Kochi. That is why he is considered as the Father of Modern Medical Toxicology in India.

Medicolegal Investigation in Poisoning

Inquest means 'to seek'. It is an enquiry into the cause of death. It is conducted where there is suspicion regarding cause of death or cause of death is to be ascertained. There are four types of inquests:

a. **Police inquest:** It is held all over India and conducted by a competent and authorised police officials. The inquest is held under Section 174 of CrPC. The police officer who conducts this is called an Investigating Officer (IO). The IO reaches the scene of the crime and takes the stock of the situation. If a person is poisoned or needs medical assistance, he is rushed to the hospital. If the victim is dead, the IO seals the scene of crime and if needed sends requisition for a photographer, fingerprint experts, ballistic experts, toxicology experts, etc. to collect evidence. He prepares a detailed report called panchnama in presence of public witnesses (panchas) who had some knowledge of the crime. This panchnama is called inquest papers. He then forwards the dead body to the medicolegal expert for a postmortem examination. On reaching the police station, a first information report (FIR) is lodged by him under relevant sections of the Indian Penal Code and investigation into the circumstances of the crime begins.
b. **Coroner inquest:** Previously, it was held in Mumbai and Kolkata under Coroner Act of 1871. It was first abolished in Kolkata, later in Mumbai. It is of historical value in India but coroner's inquest is still prevalent in many parts of the world.
c. **Magistrate inquest in poisoning:** It is held under Section 176 of CrPC and is conducted by an executive magistrate like subdivisional or district magistrate. It is considered to be superior to police inquest. It is held in following cases:
    1. Death in prison
    2. Death in police custody

3. Death due to police firing
4. Dowry deaths under Section 304 (*b*) of the Indian Penal Code
5. Any case where the government orders that inquest needs to be conducted by a magistrate.

Magistrate can order **exhumation**. Earlier, a coroner also had the power to order exhumation. In any case of death, magistrate can hold inquest even if the police has already made the inquest.

d. **Medical examiner system:** This system is prevalent in the United States of America where a forensic pathologist is appointed as a medical examiner. He conducts the postmortem and usually visits the scene of crime. Being a doctor, he is able to easily correlate poisoning with circumstances. He submits his report to the district attorney for further action. This system is considered superior to a police inquest.

Difficulties in Detecting Toxic Crimes

The following are the difficulties which are commonly faced in detecting toxic crime in India:

1. **The delay in information:** Police is unable to act on time as information regarding crime reaches the police quite late due to lack of communication facilities like telephones, etc., especially in villages or remote areas.
2. **Decomposition:** As police reaches late, the signs of decomposition may have already set in and vital evidence may be lost.
3. **Lack of medical knowledge:** As majority of police officials are ignorant about medical knowledge, they experience difficulty in correlating injuries with circumstances.
4. **Rapid disposal of dead bodies:** As per religious customs, cremation is done in Hindu and Sikh communities, if the body is cremated before arrival of police, vital evidence may be lost. Even in cases of burial, rapid decomposition may cause loss of toxicological evidence as the permission for exhumation may take some time.

Responsibilities of Physician in Poisoning

Poisoning in India is quite common. Human poisoning can be accidental, suicidal or homicidal:

1. **Accidental poisoning:** Most of the poisoning is accidental. In children, most of the poisoning is accidental as they consume tablets or syrup in the household accidentally. Accidental poisoning can occur in agricultural workers when spraying insecticides. It can occur if a person drinks unsafe water contaminated with arsenic, etc.
2. **Suicidal poisoning:** Nowadays, suicides by poisoning is very common among farmers, especially in Andhra Pradesh and Punjab. They consume insecticides when they are unable to pay agricultural loans. Aluminium phosphide and organophosphorus compounds are first choice followed by organochlorine compounds. Suicide by poisoning is also common in housewives.
3. **Homicidal poisoning:** Poison is very commonly used for homicides, especially on young children who are done away with this easily. Arsenic is commonly used followed by opium, aconite, dhatura, strychnine and potassium cyanide. If the

intention is not to kill but rob, stupefying agents like dhatura, *Cannabis indica* or chloral hydrate are used.

Medicolegal Reports in Poisoning and Alcohol Intoxication

These documents are prepared by the doctor on the request of police or investigating agencies in criminal cases like assault, rape, murder, poisoning, etc. The reports consist of two parts:

a. Facts observed on examination
b. Opinion drawn from the facts.

The report is not admitted unless the doctor testifies in the court.

Exhibits like clothing, weapon, injection, poison bottle, etc. sent for examination should be described in detail after examination and should be handed over after it is properly sealed.

Dying Declaration

It is a statement, written or verbal, of a person who is dying as a result of some unlawful act, relating to facts of cause of his death or any of the circumstances resulting in death. If there is time, a magistrate should be called. If there is an emergency, the doctor himself should record the statement. But before recording, he should certify that the person is compose mentis, i.e. he is conscious and his mental faculties are normal. The statement can be recorded by police or any other person. The statement should be noted down in the man's own words without any alteration. Leading question should be read over to the person and his signature or thumb impression should be taken at the end. If the person is able to give only partial statement, and then he becomes unconscious, only the partial statement should be recorded. The dying declaration is admissible in court as evidence even if the person was not under expectation of death at that time. It is accepted as evidence at the time of trial if the person dies. If the declarant survives, the declaration is not admitted and the person is called to provide oral evidence.

Dying Deposition

It is the statement of a person on oath before a magistrate, in the presence of the accused or his counsel, who in turn, is allowed to cross-examine the witness. The doctor should first certify whether the person is capable of making a statement or not (compose mentis). It means court by the bedside, and has greater value as compared to dying declaration.

Court Evidence in Poisoning

A doctor can be both, a common and an expert witness. When he describes the injuries on the body he becomes a common witness. But when he tells how the injuries may have been produced he acts like an expert witness. Hostile witness is the one who gives false evidence because of some interest or motive or by concealing the truth. It includes all statements made before the court, by the witness, in relation to the matter under investigation.

The oral evidence must be direct. Oral evidence is much more important than documentary evidence as it allows cross-examination. Documentary evidence is accepted by the court only on oral evidence by the person concerned.

The following are the exceptions to oral evidence in poisoning:

1. Dying declaration
2. Expert opinion expressed in a treatise may be proved in court by producing such a book, if the author is dead or cannot be found or called witness without unreasonable delay or expenses.
3. Evidence of doctor recorded in a lower court is admissible in a higher court, provided it was recorded by a magistrate in the presence of the accused.
4. Evidence given by a witness in a previous judicial proceeding, is admissible in subsequent judicial proceedings when the witness is dead or cannot be found, or is incapable of giving evidence, or cannot be called without undue delay or unreasonable expense.

Laws Related to Poisoning

The following are the laws related to poisons:

1. **Narcotic Drugs and Psychotropic Substances (NDPS) Act:** This was promulgated in 1985. A narcotic drug is defined as cocoa leaves, cannabis, opium, poppy straw and all manufactured drugs. The 'manufactured drug' means all cocoa derivatives, medicinal cannabis, opium derivatives, poppy straw concentrates and any other narcotic substance or preparation which the central government may include by notification in the list. A 'psychotropic substance' is defined as any substance natural or synthetic, or any preparation which is included in the list of psychotropic substance. It contains a list of 77 psychotropic substances. The Act provides severe punishment for the person possessing narcotic drugs. The Act differentiates between the user and the trafficker. It provides for less punishment for user who is in possession drugs for his own use. It views user with sympathy. To differentiate between the user and the trafficker the quantities of drugs in possession is defined differently for each drug. The offence in NDPS Act for traffickers is non-bailable and severe sentences are common.
2. **The Drug Act, 1940:** The purpose of this Act was to regulate import, manufacture, distribution and sale of drugs like patent or proprietary medicines, vaccines, sera, toxins, antitoxins, antigen, other biological products like vitamins, hormones and drugs commonly used for external or internal consumption. Later, insecticides, disinfectants and contraceptives were added. This Act was later changed to Drugs and Cosmetics Act, 1940 to include cosmetics. The cosmetic was defined in this Act as "Any article intended to be rubbed, poured, sprinkled or sprayed on, or introduced into, or otherwise applied to, the human body or any part thereof for cleansing, beautifying, promoting attractiveness or altering the appearance, and include any article intended for use as component of cosmetics. This Act was later amended to include Ayurvedic and Unani drugs. Under this Act, medicines are classified into Schedule H and Schedule L. Schedule H contains list of poisons which can be sold only on prescription of a Registered Medical Practitioner and these substances are labelled with the words "Schedule 'H' Drug" warning: "To be sold by retail on the prescription of Registered Medical Practitioner only".

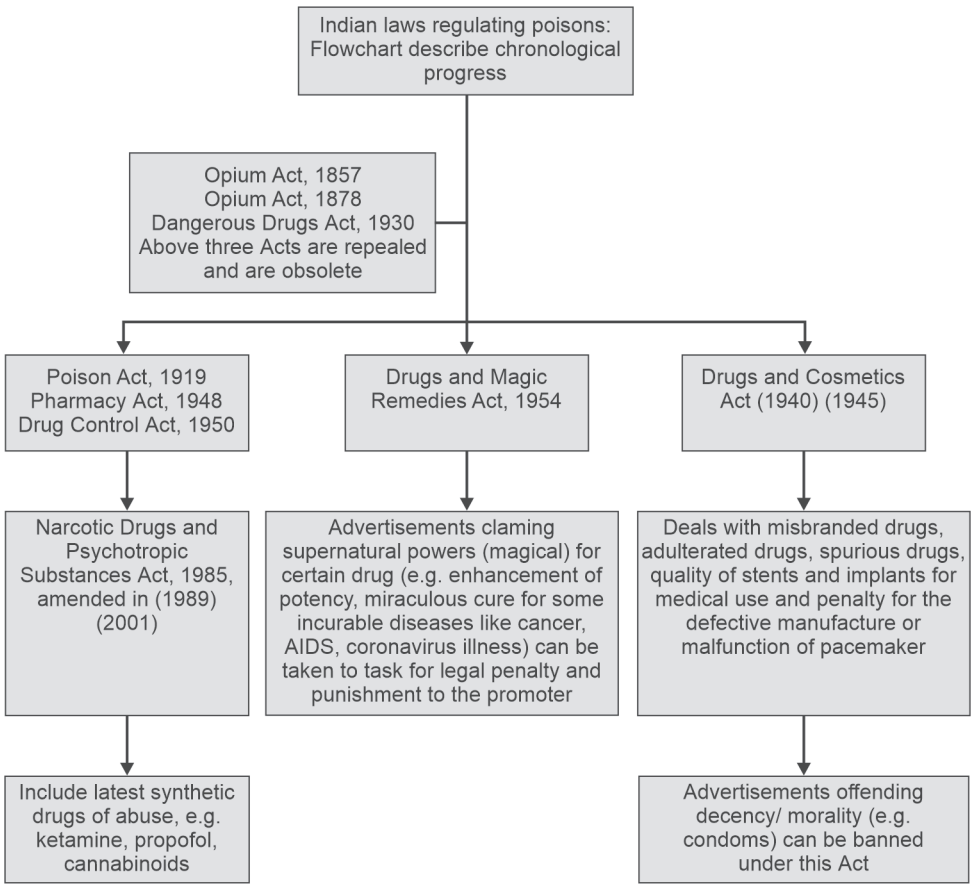
Schedule L contains a list of antibiotics, antihistaminic and other chemotherapeutic agents of recent origin. These substances are also labelled as "Schedule 'L' Drugs" warning: "To be sold by retail on the prescription of a Registered Medical Practitioner only." The prescription of a Registered Medical Practitioner must be in writing, and signed by him with date. Name and address of the patient must be given. Total amount of medicine and dose should be clearly mentioned.

3. **Pharmacy Act, 1948:** The purpose of this Act is to make better provision for the regulation of the profession of pharmacy and setting up of 'Pharmacy Councils'. Under this Act, Central Pharmacy Council was established which has control over education and examination of students entering pharmacy. The State Councils have also been constituted under this Act.
4. **Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954:** To ban advertisements in newspapers, magazines, online, to offend decency, or morality, and to prevent self-medication and treatment, resulting in accidental overdose and poisoning.

Medical Negligence and Compensation in Toxicology

It is not surprising to reveal, that the first malpractice lawsuit against treating doctors (orthopedician) was legally reported in 1953, which involved fatal iatrogenic toxicity,

Flowchart 42.1: Indian laws on regulating poisoning, drug abuse and toxicity


Indian laws regulating poisons: Flowchart describe chronological progress
Opium Act, 1857
Opium Act, 1878
Dangerous Drugs Act, 1930
Above three Acts are repealed and are obsolete
Poison Act, 1919
Pharmacy Act, 1948
Drug Control Act, 1950
Drugs and Magic Remedies Act, 1954
Drugs and Cosmetics Act (1940) (1945)
Narcotic Drugs and Psychotropic Substances Act, 1985, amended in (1989) (2001)
Advertisements claming supernatural powers (magical) for certain drug (e.g. enhancement of potency, miraculous cure for some incurable diseases like cancer, AIDS, coronavirus illness) can be taken to task for legal penalty and punishment to the promoter
Deals with misbranded drugs, adulterated drugs, spurious drugs, quality of stents and implants for medical use and penalty for the defective manufacture or malfunction of pacemaker
Include latest synthetic drugs of abuse, e.g. ketamine, propofol, cannabinoids
Advertisements offending decency/ morality (e.g. condoms) can be banned under this Act

was also filed by doctor (who was patient's father). Similarly, the highest compensation (Rs 11 crore) paid for medical negligence till now (infamously called the jackpot judgement), was also filed by doctor (patient's husband) against treating dermatologist, for causing death due to medical negligence in advising overdose of steroids and lack of hygiene, resulting in superadded infection in immunosuppressed state due to iatrogenic steroids for treating Stevens-Johnson syndrome. But it does not mean "Doctors are doctor's enemy", instead it can be interpreted that doctors have better awareness of medical know-how, and thus recognise the fatal errors in diagnosis/treatment earlier than laypersons, since in both the above described cases, the patient died during treatment inside hospital premises.

Iatrogenic Opioid Toxicity

Iatrogenic pharmacological toxicity resulting in First Indian Lawsuit for Alleged Medical Malpractice: In 1953, a 20-year-old male victim of roadside trauma with femur fracture, was prescribed opioid analgesic in fatal overdose, causing sedation with comatose state and failed to recognise the toxicity, died of due to negligence of the treating doctor, resuscitation initiated after 4 hours, only when patient's father (who was also a doctor) raised the alarm. Court held the hospital and doctor liable.

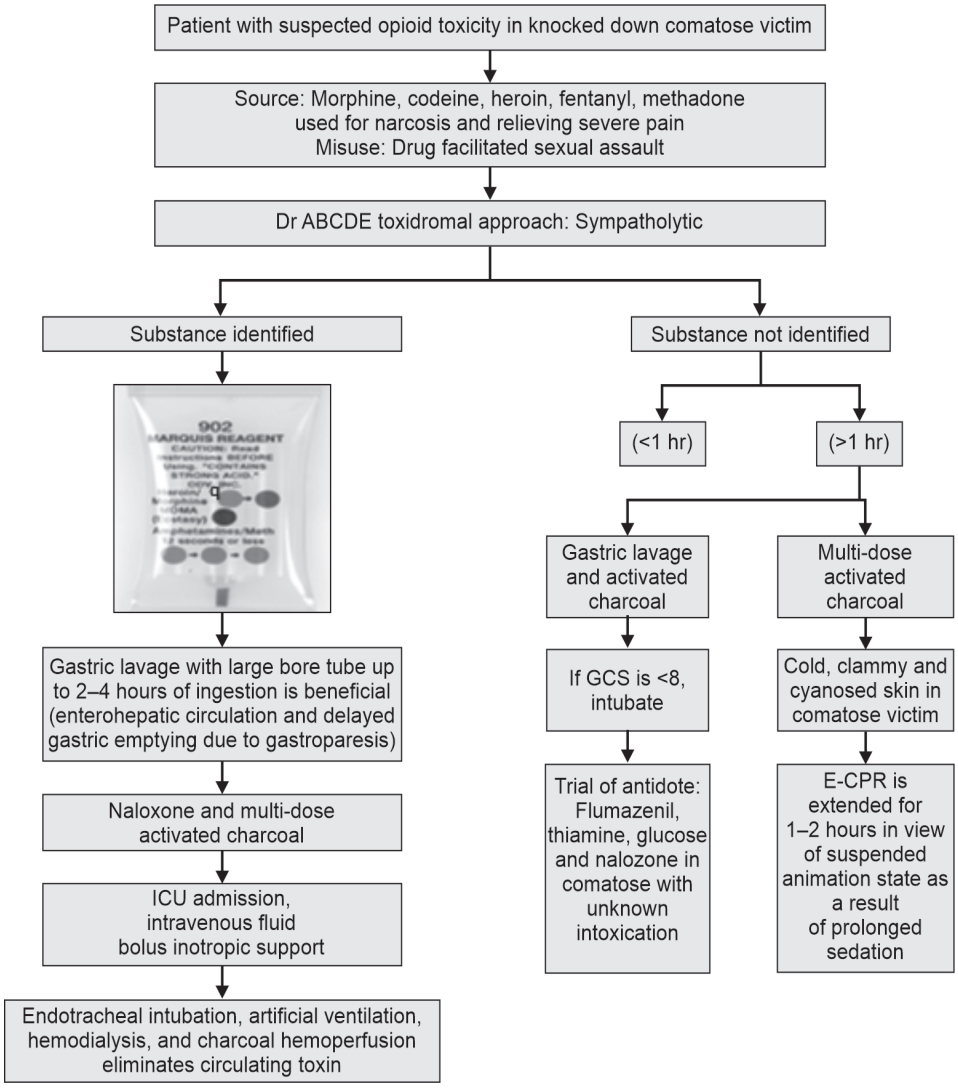
Case facts: A 20-year-old youth suffered femur fracture due to trauma, received first aid and shifted to Poona Hospital in taxi with wooden rods support tied on broken limb to Poona 200 miles away, in a taxi after a journey of about 11 hours, by his father, who was also doctor. Orthopedician admitted patient and advised urgent shifting to OT for treatment of fracture, gave morphine as analgesic without anesthetic doctor, attempted manual reduction and traction of femur fracture for 1 hour. Patient brought out of OT, remained unconscious and had breathing difficulty 2 hours later, went into respiratory failure and eventually died 4 hours later during resuscitation.[1]

Plaintiff: You made multiple attempts for about an hour to reduce my fracture, used excessive manual force in OT, and gave me opioid overdose during orthopedic procedure, failed to monitor me during narcosis, ignored my abnormal shallow breathing during unconscious state and did not secured my airway timely, resulting in compromised airway, lack of oxygen supply, causing hypoxic damage to vital centres of my brain, resuscitation initiated only after my father (who was also a doctor) raised the alarm.

Defense: I have not done any reduction of your fracture but had merely provided immobilisation with light traction, and given morphine on advise of my senior orthopedic consultant, for relieving your pain during traction in operation theatre. Although my consultant advised to give two injections of morphine to you in OT, but I have given only one to you, thus it is not an overdose. And as per my observation, I have documented cause of death (without postmortem) as cerebral fat embolism due to long bone fracture, as it may have occurred due to circulation of fat globules released from bone marrow of broken femur, thus blocking the supply of oxygen to vital area of brain.

Result: Patient's father filed lawsuit of alleged medical negligence against hospital and doctor: Court held them negligent—liable to pay damages under Fatal Accidents Act, 1855—monetary compensation to the patient's father.

Flowchart 42.2: Algorithm for opioid toxicity identification and investigation


Patient with suspected opioid toxicity in knocked down comatose victim
Source: Morphine, codeine, heroin, fentanyl, methadone used for narcosis and relieving severe pain
Misuse: Drug facilitated sexual assault
Dr ABCDE toxidromal approach: Sympatholytic
Substance identified
Substance not identified
(<1 hr)
(>1 hr)
Gastric lavage with large bore tube up to 2–4 hours of ingestion is beneficial (enterohepatic circulation and delayed gastric emptying due to gastroparesis)
Naloxone and multi-dose activated charcoal
ICU admission, intravenous fluid bolus inotropic support
Endotracheal intubation, artificial ventilation, hemodialysis, and charcoal hemoperfusion eliminates circulating toxin
Gastric lavage and activated charcoal
If GCS is <8, intubate
Trial of antidote: Flumazenil, thiamine, glucose and nalozone in comatose with unknown intoxication
Multi-dose activated charcoal
Cold, clammy and cyanosed skin in comatose victim
E-CPR is extended for 1–2 hours in view of suspended animation state as a result of prolonged sedation

Case discussion: The court held them guilty of negligence and wrongful acts on the following grounds:

- The clinical notes did not justify the reasons doctor has stated for delaying his treatment of unconsciousness or surgical reduction of fracture.
- Nowhere in the case history had doctor mentioned that he had given only one injection of morphine, instead of two. When asked during cross examination about two injections, doctor told that he has given only one injection, and he forgot to give second injection of morphine.
- Doctor's plea that fat embolism must have set in right from time of the accident or on account of inadequate immobilisation and hazards of long journey in taxi, was not justified as there was no mention of this in the clinical notes, neither any

symptoms nor signs were mentioned which occur many hours prior to setting of pulmonary symptoms, nor did he warned patient's father of this risk of embolism.
- The letter exchanged between doctor and patient's father later, clearly stated that he had done fracture reduction.

Court observed: A person who holds himself out ready to give medical advice and treatment impliedly holds forth that he is possessed of skill and knowledge for the Purpose. Such a person when consulted by a patient, owes certain duties, namely a duty of care in deciding whether to undertake the case, a duty of care in deciding what treatment to give, and a duty of care in the administration of that treatment. A breach of any of these duties gives a right of action of negligence against him. The medical practitioner has a discretion in choosing the treatment which he proposes to give to the patient and such discretion is wider in cases of emergency, but, he must bring to his task a reasonable degree of skill and knowledge and must exercise a reasonable degree of care according to the circumstances of each case.[1]

Alleged Case of Medical Negligence, Where there was no Toxicologist

Allegation of inadequately qualified/trained health care personnel in managing venomous snakebite victim:

Case facts: In 1999, patient had a snakebite and was taken to the hospital of the doctor (OP) immediately. The doctor (OP) injected 14 vials of ASV within 10 hours of admission. The patient was thereafter transferred to the Medical College Hospital (MCH) where he was treated and later discharged. Based on allegations of negligence that there was no toxicologist, and MBBS doctor treated the patient by unnecessary overdosing of antidote in short time, district consumer court gave directions to pay to the complainant a sum of Rs 15,975 with costs of Rs. 1000 within one month from the date of receipt of the order of the Forum. Opposite party (OP) doctor and hospital appealed against the order in State Consumer Forum, and won the case, acquitted of negligence charges.

Patient's allegation/s of medical negligence: It was alleged that it was unnecessary to administer fourteen vials of ASV (anti-snake venom), and that too within 10 hours. It was alleged that although one senior doctor had the requisite expertise to treat snakebites, the doctor (OP) who was not competent treated the patient.

Doctor's defense: It was stated that an MBBS doctor is capable of treating snake-bites and the doctor (OP) was an MBBS. It was further stated that senior doctor was an anesthetist and was actually called to assist the doctor (OP). It was stated that if 14 vials of ASV had not been given to the patient there was eminent danger to the life of the patient. It was pointed out that the medical expert had stated in court that, "there are no hard and fast rules that a certain number of vials should be administered".

Findings of the state consumer court: The court relying on the expert's statement that there was no standard protocol regarding the number of vials that should be administered to a patient of snakebite, held that the doctor (OP) was not negligent in administering 14 vials of ASV to the patient in 10 hours. The court held that an MBBS doctor was competent to handle a snakebite patient. Hence, the doctor (OP) was not held negligent.

Illustrative Cases in Homicidal Poisoning

1. Siddhartha Gautama (known as the Buddha), by some accounts, may have died of mushroom poisoning around 479 BC, although this claim has not been universally accepted.
2. Found about 60 miles from his home, a middle aged man at first appeared to have died in the accident that put his car in a ditch. A partially burned fuse, however, hung from the open gas tank. Multiple bruises and contusions further complicated the investigation. His blood alcohol was only 23 mg/dl, and no drugs or toxins were detected. The break in the case came when DNA testing was done on the stamp of a suicide letter that was thought to have been sent by the victim. Instead, his wife's DNA was discovered on the stamp. When confronted, she confessed to his murder. She had taken the leaves and stems of three *Aconitum napellus* plants and boiled them. She mixed the liquid with a few triazolam tablets in a bottle of red wine. Three and a half hours after consuming the wine, her husband was dead. His injuries were due to being dragged up and then down the stairs when she decided to move his body out of the house. Sitting in her dead husband's lap, she drove the car to its point of discovery and pushed it into the ditch. She attempted to set the vehicle ablaze and left the scene to hail a taxi for her return home. Liquid chromatography-tandem mass spectrometry (LC-MS/MS) demonstrated the presence of aconitine in his urine, liver, and kidneys.

   This case illustrates that medicolegal reporting and crime scene investigation is very important, to suspect homicides and murders simulated as roadside accidents.

Duties of Doctor in Poisoning

Duties of a medical practitioner in suspected cases of poisoning are:

1. Medical: Includes treatment of the patient. If patient is serious, medical duties will take precedence over legal duties.
2. Legal:
   a. Information to police: All cases of poisoning, whether suicidal, homicidal or accidental. This applies to both government and private practitioners. Although the Section 309 of IPC for suicidal attempt has been repealed, so the suicidal victim cannot be punished for his act, as its due to mental illness. But, abatement of suicide by family members, in laws or any person who blackmails the victim, to abate killing self, needs to be punished and prevented for future harms possible.
   b. Preservation of samples in chain of custody: Blood, urine, gastric lavage, clothes of the victim, for detection of suspected poison.
   c. Arrangement of dying declaration in critically ill victim, of suspected homicide.
   d. Information to public health authorities: In case of food poisoning in mid-day meal, long-term hooch tragedy by illegal country liquor with methanol poisoning, to punish and penalise the source of mass casualties under Disaster Management.

BIBLIOGRAPHY

1. Judgement Citation: Supreme Court of India decision in Laxman Balkrishna Joshi vs Trimbak Bapu Godbole and another. 1969 AIR 128, 1969 SCR (1) 206. Link: https://indiankanoon.org/doc/297399.
2. Modi (Author), K. Kannan (Editor). *A Textbook of Medical Jurisprudence and Toxicology*. 26th Ed. Lexis Nexis, 2016.
3. Pillay VV. Comprehensive Medical Toxicology. 3rd. Ed. 2018. Section IV: Biotoxicology. Chapter 19. Food Poisoning. Box.19.3 Mushrooms: Historical aspects. p 1064-65.
4. Sharma, RK. *Concise Textbook of Forensic Medicine and Toxicology*. 3rd Ed. 2011.
5. Van Landeghem A, De Letter E, Lambert W, et al. Aconitine involvement in an unusual homicide case. *Int J Legal Med* 2007;121:214–19.

Chapter
43

Adoption Laws in India

Avinash Thumalapalli

ADOPTION

- Process by which child is severed legally from his/her biological parents.
- Child becomes the lawful child of his/her adoptive parents
- All the rights, privileges and responsibilities post adoption are similar to that in case of a biological child.

Laws of Adoption in India (As on Nov 2017)

1. Hindu Adoption Maintenance Act, 1956
2. Juvenile Justice (Care and Protection of Children Act), 2015 (JJ Act) Model JJ Rules, 2016
3. Adoption Regulations 2017

Hindu Adoption Maintenance Act

- Only a Hindu, Buddhist, Jain, or Sikh husband above the age of 18 can adopt under this Act only with the consent of his living wife (husband is the adopter and wife is merely consenter).
- A single female (unmarried, divorcee or widow) can also adopt.
- A person having a male child cannot adopt a male child.
- A person having a girl child cannot adopt a girl child.
- Age difference between the adoptive father and the adoptive girl child to be at least 21 years.
- The child has to be below 15 years of age.
- Provision of payment or reward and any contravention shall be punishable.
- Adoption can be concluded through a registered adoption deed subject to compliance with the provisions of the Act.

Courts permission to adopt under this act is required only in the following cases

- Where both the father and mother are dead.
- Where both the father and mother have completely and finally renounced the world.
- Where both the father and mother have abandoned the child.
- Where both the father and mother have been declared to be of unsound mind by the court concerned.
- Where the parentage of the child is not known. Valid adoption cannot be cancelled.

Juvenile Justice Act, Adoption

- A secular Act (any body irrespective of religion can adopt a child under this Act).
- Nothing in this Act shall apply to adoption under HAMA.
- All inter-country adoptions shall be done as per provisions of this Act and adoption.
- Regulations framed by the authority: Central Adoption Resource Authority (India is a Signatory to Hague Convention on Inter-country Adoption).
- Children up to the age of 18 can be adopted under this Act.
- Orphan, abandoned and surrendered (OAS) children declared legally free for adoption by CWC can be placed in in-country and inter-country adoptions.
- Children of relatives, as defined in the JJ Act, can be adopted by an in-country parent.
- Children of relatives, as defined in the JJ Act, can be adopted by an inter-country parent.

Eligibility of Prospective Adoptive Parents

- A couple/single parent can adopt.
- Single male not eligible to adopt a girl child.
- Prospective adoptive parents (PAPs) age eligibility criteria are defined.
- Minimum 2 years stable marital relationship is mandatory.
- PAPs with 3 or more children shall not be eligible to adopt a normal OAS child.
- Eligibility and suitability of the PAPs are ascertained through a home study.

Post-adoption follow-up of the adoptive family both in case of in-country and inter-country is undertaken for 2 years.

Court Procedure (Including Adoption Order Annulment) is defined in the Act.

Attention: Guardians and Ward Act, 1890 is not an Adoption Law.

THE ROLE OF A PEDIATRICIAN

Pre-Adoption

- Discourage illegal adoptions and inform prospective adoptive parents the law of the land and the procedure involved.
- It is imperative to understand that one of the main objectives of adoption in India is to ensure children with disabilities/not 'normal' children too have right to access to loving family care.
- Pre-adoption visit: Health care professionals should discuss with parents pre-adoption health records, and clarify the same.
- It is a challenge when biological parentage is not known as there is potential complication of tracing genetic traits.

Comprehensive Medical Evaluation of the Newly Adopted Child: Complete Physical Examination

- Vital signs
- Growth points
- Complete physical examination, with emphasis on skin and genitalia

- Neurological examination with emphasis on developmental and neurological abnormalities.

Diagnostic Testing

- Infectious diseases: HBV, HCV, HIV 1 and 2
  Tuberculosis—PPD
  Stool pathogens
- Anemia screening
- Nutritional and metabolic screening
- Screen for hemoglobinopathies
- Blood lead concentration
- Newborn screening
- Rickets screening

Immunization

Evaluate immunization status and administer age appropriate vaccination, if no records: Immunize as a unvaccinated child.

Other

- Hearing screening
- Vision: Examination, refractory error and fundus
- Dental: Caries and pediatric dentistry referral
- Developmental screening and assessment and intervention if required.
- Speech, language, occupational and physical therapy referral when needed.
- Address unique behavioral issues and psychological challenges that many adopted children experience.

Supporting Adoptive Families and the Child

- Parent should tell children if they are adopted, and pediatricians should help them address challenges in rearing an adopted child.
- Clinicians should teach adoptive parents to be open about the nature of the adoption with their child while still establishing that an adopted family is still a real family. (No established time: Children do not understand difference between biological/adoptive family until 3.)
- Pediatrician is an important resource and advisor for parents dealing with psychological and emotional problems facing adopted children.
- It is becoming increasingly important for pediatricians to be aware of and knowledgeable about adoption, and that they play an important role in helping families and the child deal with the differences, the losses, and the many other issues surrounding the adoption.

Resources

1. Central Adoption Resource Authority, Government of India Website: http://www.cara.nic.in/
2. Amercian Academy of Pediatrics Council on Foster Care, Adoption and Kinship Care weblink: https://www.aap.org/en-us/about-the-aap/Committees-Councils-Sections/Council-on-Foster-Care-Adoption-Kinship/Pages/Foster-Care-Adoption-Kinship.aspx.

Chapter
44

Genital Trauma in Girls and Medicolegal Concern

Rohini S Deshpande

Genital trauma in pediatric and adolescent age is a common emergency although its incidence is difficult to put forward. Children are vulnerable to trauma on playground, at home or while being with their friends or it can be a sexual assault. Quite often this may happen when children left to play on their own especially in garden or any play area. In such situation parents seek help immediately due to agony of pain and fear of trauma, bleeding associated with it. The nature of injury can be trivial to serious in nature.

Child is often brought either to gynecologist, pediatrician, surgeon or to the general practitioner. Accidental genital injuries are usually caused by fall across bicycle bar. The vagina, urethra and hymen area is usually spared because of protection provided by overlapping labia. Bruising, hematomas are most common presentations.

When the injury involves genital organs it is a matter of serious concern and always it should be viewed with suspicion of sexual assault and medicolegal thought should be given.

MEDICOLEGAL ISSUES

1. Any suspicious genital trauma in children under age of 18 years should be notified to police in all the circumstances and irrespective of nature of the injury. This is mandatory under POCSO Act (Protection of Children from Sexual Offences Act, 2012).
2. **Section 3 of POCSO Act:** It has provision of any penetrative sexual assault (insertion, penetration, manipulation with penis, any body part, or any object into the vagina, mouth, urethra, or anus of a child) . Any penetrative injury in girl child should be viewed with suspicion of sexual assault.

Section 19–21 of POCSO Act: Mandatory Reporting of Offences

- Section 19 (1), any person who has knowledge of sexual offence committed or likely to be committed on a child.
- Section 21, failure to report or record is punishable.

All offences under POCSO Act are considered as grave offences. Hence, they are nonbailable and cognisable and the trial is to be conducted by court of sessions.

Punishment for Failure to Report or Record a Case

1. Any person, who fails to report the commission of an offence under sub-Section (1) of Section 19 or Section 20 or who fails to record such offence under sub-Section (2) of Section 19 shall be punished with imprisonment of either description which may extend to six months or with fine or with both.
2. Any person, being in-charge of any company or an institution (by whatever name called) who fails to report the commission of an offence under sub-Section (1) of Section 19 in respect of a subordinate under his control, shall be punished with imprisonment for a term which may extend to one year and with fine.
3. The provisions of sub-Section (1) shall not apply to a child under this Act.

Role of Doctors and do's in Attending a Girl with Genital Trauma under POCSO Act

1. It is mandatory to inform local police or Special Juvenile Police Unit (SJPU) as the case may be under Section 20 and failure to report shall be punished with imprisonment of either description which may extend to six months or with fine or with both under Section 21.
2. Medical examination of a child (Section 27): It should be conducted in accordance with (Section 164 of Criminal Procedure, 1973 (2 of 1974) not waiting for FIR or complaint to be registered. Medical examination shall be conducted by a woman doctor in presence of parents of child or any other person whom the child poses trust or confidence or in absence of relative then examination is conducted in presence of woman nominated by head of the medical institution.
3. Emergency medical care shall be rendered in such a manner as to protect privacy of the child and in presence of parent or guardian or any other person in whom the child has trust and confidence without demanding any legal or magisterial requisition or other documentation as a prerequisite to rendering the care.
4. The registered medical practitioner rendering emergency medical care shall provide treatment to all injuries, treatment for exposure to STD including prophylaxis, treatment for exposure to HIV including prophylaxis to HIV, possible pregnancy and emergency contraception as need be and also above all psychological care to the child and parent.
5. POCSO Act only mentions reporting and not investigating by medical provider or lodging FIR. So, the doctor can go ahead with the treatment and does not require to wait for the authorities to take action.
6. No person shall incur any liability, whether civil or criminal, for giving the information in good faith for the purpose of sub-Section.[1]

Consent

Consent of the parents or guardian should be obtained prior to the examination of the child. Section 3 of the Indian Majority Act, 1875 speaks of attainment of majority on the completion of 18 years of age. Hence, if age of the child is below 18 years then consent of parents/guardians is essential.

Documentation and Record-keeping of Vital Data

1. Name, age of the child, address should be noted. Relevant information of parents/guardians such as name, address, occupation should be recorded. To prove age X-ray of the wrist may be taken.

2. Identity marks of the child should be taken.
3. Time and date of admission and examination, time and date of injury should be noted.
4. All the clothes of the child should be inspected and preserved.

Approach to Examination of a Child with Genital Trauma

History: In small children, history is often given by a relative/parent who has witnessed the injury.

Careful note must be done of who witnessed/noticed it and how it happened, location of the place and the course of events. If child is in position to talk then history can be obtained from child herself and note should be made.

Examination with Consent of Parents or Guardian

This is a challenging part. The child is usually in fear, pain. Written and informed consent of the parents should be taken.

With consent of parents the examination is undertaken in appropriate place where proper inspection facility is available. In case there is any small hematoma or bruising ice packs can relieve the pain. In case of severe injury examination under anesthesia is recommended. If child is brought by parents in shock then resuscitation should be done immediately.

General examination findings will include mental status, consciousness, vital signs, any marks or bruises, any other injuries on the body. If present complete narration of the nature of injury should be documented. Secondary sexual characters should be mentioned if developed.

Systemic examination of cardiorespiratory system, abdominal examination should be performed and documented. Special inquiry should be made whether the child has voided urine or not.

Genital examination: Underclothing staining should be noted and clothes should be preserved and if soiled with blood or any other material like soil/semen it should be mentioned:

1. Extent and site of injury involving vulva, labia, hymen, introitus, vagina, urethra, perineum, anus, rectum, bladder should be mentioned.
   Medicolegal point: If it is involving beyond hymen then it is a penetrating type of injury and high possibility of sexual assault should be considered.
2. The type of tissue injury like tear, bruising, bleeding vessel, should be narrated.
3. If any foreign body is noted it should be mentioned.

Investigations and Treatment

It depends on general condition of the child and type of injury/assualt. If it is trivial and simple then local debridement, cleaning of wound, local antibiotics cream can be given. In this case, it can be treated on outpatient basis and follow up is suggested.

Basic investigations include blood test, blood group and CBC and screening for infections such as VDRL, HIV. Ultrasound examination can be performed if need be.

If the nature of the injury is deep, penetrating then accordingly assessment is performed. Initial resuscitation is performed with IV fluids, supportive measures such

as oxygen, antibiotics, inotrops, depending on the condition of child and extent of shock.

In case the minor girl is found pregnant, should be carried out as per the MTP Act, taking consent of parents/legal guardians and products of conception to be handed over to police officer (preserved in bottle of normal saline and for further investigations, bottle is sealed).

Child may need debridement, catheterization, suturing and sometimes repair and reconstruction of damaged parts. Help of specialist surgeon can be taken if need be.

Notes of examination and procedure performed are recorded in the case file.

Counseling of the Parents/Guardian

Parents should be informed about the examination findings and course of treatment and follow-up instructions should be given.

Information to Police

All the cases should be notified to police. Regional police station has to be contacted and its note should be kept. Police will come for the inquiry and further investigation into the matter will be undertaken by them. Any material for evidence such as clothing of the child/underclothes should be handed over to the police.

CONCLUSION

Genital trauma in girls is matter of serious concern from medicolegal point of view. Reporting of such cases to police is mandatory under POCSO Act. First aid and treatment should be given to the child at the earliest. Parents should be counselled about the nature of the injury. Case notes should be written meticulously and records should be preserved.

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Medicolegal Problems and Solutions

A Doctor's and Practitioner's Guide

The doctor–patient relationship has changed drastically during the last few decades. Changes which have come with the introduction of Consumer Protection Act have brought about the trend of defensive practice among doctors and made the doctor–patient relationship more formal.

There has been a general decline in the status of the doctor as mob harassment and lawsuits have increased exponentially, contributing to even more strained doctor–patient relationship. Despite being good in their profession, when it comes to taking due measures to avoid mistakes or to handle medicolegal situations, only a few doctors are able to face the situation adeptly. Record-keeping, informed consent, and proper documentation form the basis of safe medical practice. Unexpected death in hospital or OT is a tricky issue and how to deal with it, how to manage the mob and media, when to send the body for postmortem examination, and how to complete the documentation in such cases, are all incorporated in the book.

This state-of-the-art book contains 44 chapters, based on day-to-day medicolegal issues, contributed by authors with expertise in medicolegal knowledge and patientcare. The text is divided into eight sections •Critical Patients, •Procedural Complications, •Errors in Practice and Unexpected Outcome, •Difficult Situations, •Statutory Situations, •Negligence, •Administrative Problems and •Miscellaneous Topics.

This book aims to meet the requirements of not only the practicing doctors but also the undergraduate and postgraduate students, medicolegal consultants and other stakeholders in legal profession, law enforcement agencies and judicial officers/judges.

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